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CHEMICAL LAND HOLDINGS, INC.

CLH

May 15, 2001

U.S. Environmental Protection Agency, Region II
Emergency and Remedial Response Division
290 Broadway, 19th Floor, Room W-20
New York, NY 10007-1866

Attention: Ms. Sharon Jaffess
Remedial Project Manager

Subject: Creel Angler Survey – Response to EPA Comments
Chemical Land Holdings, Inc.
Administrative Order on Consent Index No. II-CERCLA-0117

Reference: EPA Letter dated April 20, 2001
Diamond Alkali Superfund Site – Passaic River Study Area
Creel/Angler Survey

Dear Ms. Jaffess:

Please find enclosed CLH's responses to the comments provided by the United States Environmental Protection Agency (EPA) and the New Jersey Department of Environmental Protection (NJDEP) in the above-referenced letter.

In two years of developing, implementing, and administering the Passaic River Creel Angler Survey Work Plan (CASWP), CLH has worked diligently to produce a state-of-the-art preeminent data set to support a scientifically-defensible, reliable risk assessment. Although EPA's comments hold CLH to a higher standard than EPA has ever set for itself, its comments exposed no flaw with the CAS, and, indeed, demonstrate that this CAS is more thorough and will result in more complete data than those referenced and previously relied upon by EPA.

That said, CLH offers several general observations about EPA's comments. First, CLH counted 50 comments of which 10 are variously repeated within the letter, leaving 40 comments requiring separate responses. Several of these comments have been considered previously but have not yet achieved closure. In addition, about half of EPA's April 2001 comments relate to the subject of the design and administration of the CASWP, while the remainder address issues more properly reserved for consideration during the conduct of the risk assessment. CLH agrees that these two activities are fundamentally linked, and the CAS was designed in consideration of the data use objectives and quality requirements attendant upon and supportive of the risk assessment. The lack of detail existing in and/or disagreements between the Agency and CLH on the data analysis approach are not, in CLH's opinion, sufficient justification on the part of the Agency to reject the use of this preeminent data set in the risk assessment. Please recall from the Risk Assessment Kick-off Meeting on July 19, 2000 that Ms. Janet Conetta explained that she anticipated numerous meetings and extensive debate regarding the development of the risk assessment – this

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discussion/debate will be considerably improved in the context of supportable, site-specific data. Conversely, a lack of such site-specific data will render the risk assessment results unreliable or even irrelevant, given the inapposite nature of and demonstrable flaws in the default values available to EPA.

CLH categorically rejects EPA's repeated assertions throughout its comments that the CAS is designed in a manner that will lead to underestimates of exposure in the risk assessment. The design anticipates and incorporates the requirements necessary to support an unbiased risk assessment. The likelihood of this assessment to under- or overestimate risk will result from decisions made in the choice of risk assessment methodology and analysis of exposure-related data. The CAS can best serve the risk assessment by collecting the most accurate and reliable information from Study Area anglers – i.e., site-specific data that truly represent angling activity in the Study Area.

Many of EPA's comments indicate a preference for alternative survey methodology to that employed in the CAS. While there exists no professional consensus regarding the ideal method for conducting an angler survey to support risk assessment, CLH has optimized the CAS by encouraging participation from anglers and collecting accurate and reliable information. This has been accomplished and validated by applying concepts from literature related to survey research and risk assessment, and by incorporating insight gained from the extensive pretest activities conducted as prelude to the CAS.

Furthermore, the application of sound statistical principles in the design of the CAS will facilitate defensible statistical interpretation of the data in the risk assessment. Based on a thorough review by its Expert Panel, convened in lieu of EPA's participation in this essential data collection effort, CLH is confident that the CAS represents an unprecedented effort of the highest quality. The attached table (also provided in response to EPA comment 1.1.2) compares elements of the CAS to elements of angler studies that EPA has directed CLH to use for default, non-site-specific fish consumption rates and to elements of the survey that supported the risk assessment for the Hudson River (EPA's "go-by" document). This table illustrates that the CAS meets a higher standard of practice than any of the studies upon which EPA Region 2 has relied for decision-making.

CLH appreciates EPA's "willing[ness] to meet one more time...to bring the discussions of the Survey Work Plan to a close." Unfortunately, prior meetings have not brought to a close issues related to the CAS. Rest assured that CLH would not continue its efforts to do so were the CAS not so integral to develop site-specific data to assure a reliable assessment of risk. Please recall the recent history of this activity:

April 6, 1999 EPA approved (with the exception of the included schedule) the Ecological Sampling Plan – which required preparation and submittal of a Creel Angler Survey Work Plan.

May 3, 1999 CLH agreed to perform ESP, including the Creel Angler Survey

June 29, 1999 CLH submitted the draft Creel Angler Survey Work Plan.

January 27, 2000 EPA provided “informal” comments on June 1999 draft Creel Angler Survey Work Plan

April 27, 2000 EPA notified CLH that the Creel Angler Survey Work Plan was disapproved, citing a suppression effect: “Specifically, we believe that the long-standing existence of an advisory against consumption...from the Passaic River...make [sic] it impossible to obtain accurate responses from those surveyed, and hence, valid data.”

May 1, 2000 CLH requested a meeting on May 23, 2000 to discuss the disapproval.

May 23, 2000 EPA/CLH meeting.

CLH demonstrated that

- suppression due to advisories is insignificant;
- the ingestion rates EPA directed CLH to use from the Exposure Factors Handbook were not adjusted for suppression; and
- there is no precedent in CERCLA for suppression effect adjustments in risk assessment.

EPA agreed that a representative Creel Angler Survey could be performed, but changed its basis for denying conduct of the Survey to an expression of concern that the Survey would take 2-4 years to complete. CLH refuted this unfounded assertion, to no avail (reference the Meeting Notes of May 23, 2000).

In addition, EPA posed a criticism that the latest version of the Creel Angler Survey Work Plan was not responsive to the Agency’s 1996 comments (these were provided to CLH in a letter dated April 15, 1996 providing comments on the draft Ecological Sampling Plan); CLH committed to investigate.

June 16, 2000 Ms. Carol Dinkins submitted a letter on behalf of CLH expressing concern over the process that lead to the disallowance of the Creel Angler Survey, requesting that the Agency reconsider the April 2000 directive.

June 23, 2000 CLH submitted a Response-to-Comments document demonstrating how the June 1999 version of the Work Plan was responsive to the Agency’s April 15, 1996 comments received in connection with the December 1995 submission of the draft Ecological Sampling Plan.

- July 6, 2000 CLH notified EPA of its intent to commence the CAS in August 2000, and submitted a Revised Creel Angler Survey Work Plan responsive to Agency comments received via e-mail on January 27, 2000, along with a Response-to-Comments document addressing each of the comments and explaining how they were addressed in the accompanying version of the Work Plan.
- August 2000 CLH commenced the Creel Angler Survey.
- August 22, 2000 CLH requested that EPA rescind its decision to forego collecting the creel angler data and requested a meeting with the Region 2 Regional Administrator
- October 4, 2000 CLH meeting with Richard Caspe, Director, ERRD, USEPA Region 2. The history of the Creel Angler Survey was reviewed and discussed, and technical details responsive to EPA's prior concerns were explained. Although it did not rescind its directive, EPA and CLH reached the following agreements:
- CLH agreed to provide the update Creel Angler Survey Work Plan, and other information related to the Survey (which it did October 24, 2000 and November 9, 2000 under signature of Ms. Carol Dinkins).
 - CLH agreed to provide information relating to the CAS to allow EPA staff to perform oversight (which it has done, and continues to do).
 - EPA agreed to review the materials presented, plus the additional materials requested, and provide its response "within a couple of weeks."
- January 30, 2001 EPA submitted the letter "Schedule for Further Activities" which acknowledges improvements to the Creel Angler Survey Work Plan and promises to provide, within a "few weeks," comments that demonstrate that the Work Plan still does not meet all of EPA's concerns. EPA does, however, agree to consider a creel/angler survey report submitted by October 2001 as part of any risk assessment" drafted for the Passaic River.
- April 20, 2001 EPA sent comment letter that is the subject of this response.

As demonstrated by the lengthy history of information exchange, without apparent success at promoting technical concurrence, CLH feels it is important to meet, once again, to review this final set of EPA comments. CLH believes that the responses provided in the attached Response to Comments document clearly and completely address each of the Agency's comments. If we are to "bring discussions of the Survey Work Plan to a close" we must have an exchange of opinions between the technical teams from EPA and CLH to determine, and document,

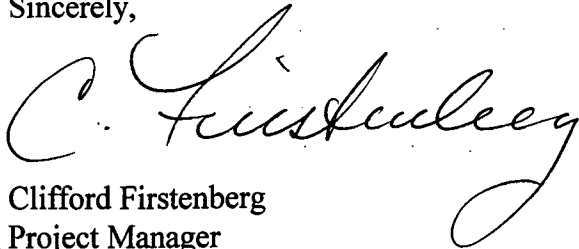
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concurrence or disagreement on each item. It is only in this manner that we will preclude yet another iteration of responses that are submitted, only to be answered with another set of comments from the Agency.

CLH looks forward to meeting with you and the EPA technical and management team on June 7 or such other date that is mutually convenient to review each of these responses to (1) determine that they were responsive to the Agency's comment, (2) provide further explanation or information if necessary, and (3) come to agreement on the sufficiency of the response, inclusive of additional discussion provided at the meeting.

Please include this letter and the attached Response to Comments in the official administrative record for this Administrative Order on Consent.

Sincerely,



Clifford Firstenberg
Project Manager
On behalf of Occidental Chemical Corporation
(as successor to Diamond Shamrock Chemicals Company)

(2 copies sent)

Enclosures:

1. Table: Comparison of the Passaic River Creel/Angler Survey to Surveys Used to Derive EPA's Default Fish Consumption Rate and New York Survey Used in Hudson River Risk Assessment
2. Response to Comments on Creel Angler Survey Prepared by US Environmental Protection Agency and New Jersey Department of Environmental Protection (April 20, 2001 Letter from USEPA Region 2) May 15, 2001

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Table: Comparison of the Passaic River Creel/Angler Survey to Surveys Used to Derive EPA's Default Fish Consumption Rate and New York Survey Used in Hudson River Risk Assessment

Characteristics of Quality Angler Surveys	Surveys Used to Derive EPA's Default Fish Consumption Rate					
	Passaic River Survey	Maine Survey ^a	Lake Ontario Survey ^b	1989 Michigan Survey ^c	1993 Michigan Survey ^d	New York Survey ^e
Pretested	X	X	?	X	X	?
Reviewed by expert panel	X					
On-site interview	X					
Information on licensed and unlicensed anglers	X					
Multilingual	X					
Capture illiterate anglers	X					
Minimal recall burden	X		X	X	X	
Information on fishing activity for entire year	X	X	X			X
Information on fish consumption for entire year	X	X	X		X	
Capture effect of seasonality on fishing activity over entire year	X		X			
Capture effect of seasonality on consumption of fish over a year	X		X		X	
Information on shellfish and fish	X					
Information on night angling	X	?	?	?	?	?
Information on fish consumption specific to waterbody	X			X	X	X
Capture how long angler has fished at a specific waterbody	X					
Able to validate species identification	X					
Measure each fish harvested (e.g., length, weight)	X		X		X	
Composition of fish consumed (i.e., number, species)	X	X	X			
Information on number of meals			X	X	X	X
Portion size model			X	X	X	
Information on preparation/cooking methods	X	X	X	X	X	X
Information on parts consumed by species	X					
Information on fish consumed obtained from other individuals ^f		X				
Demographics of anglers	X	X	X		X	X
Fish consumption information for women of childbearing age	X	X	X	X	X	X
Fish consumption information for pregnant or nursing mothers	X					
Fish consumption information for children	X	X		X		
Information on awareness of advisories	X	X	X	X	X	X
Information on effect of advisory	X	X	X	X	X	X
Established/documented data quality objectives	X	X	?	X	X	?
Met data quality objectives	Pending	X	?		X	?
High respondent participation (> 60%)	X	X				
Information on nonrespondents	X			X		X
Information on anglers at every location fished in the survey area	X					
Information to estimate the size of the exposed population	X					

^a Ebert *et al.* (1993)

^b Connelly *et al.* (1996)

^c West *et al.* (1989)

^d West *et al.* (1993)

^e Connelly *et al.* (1992) used in Hudson River risk assessment

^f Recreationally caught fish from other members of the household or individuals outside of the household.

Response to Comments on Creel Angler Survey
Prepared by
US Environmental Protection Agency and
New Jersey Department of Environmental Protection
(April 20, 2001 Letter from USEPA Region 2)
May 15, 2001

INTRODUCTION

CLH categorically rejects EPA's repeated assertions throughout its comments that the Creel Angler Survey (CAS) is designed in a manner that will lead to underestimates of exposure in the risk assessment. The design anticipates and incorporates the requirements necessary to support an unbiased risk assessment. The likelihood of this assessment to under- or overestimate risk will result from decisions made in the choice of risk assessment methodology and analysis of exposure-related data. The CAS can best serve the risk assessment by collecting the most accurate and reliable information from Study Area anglers – i.e., site-specific data that truly represent angling activity in the Study Area.

Many of EPA's comments indicate a preference for alternative survey methodology to that employed in the CAS. While there exists no professional consensus regarding the ideal method for conducting an angler survey to support risk assessment, CLH has optimized the CAS by encouraging participation from anglers and collecting accurate and reliable information. This has been accomplished and validated by applying concepts from literature related to survey research and risk assessment, and by incorporating insight gained from the extensive pretest activities conducted as prelude to the CAS.

CLH offers several general observations about EPA's comments. First, CLH counted 50 comments of which 10 are variously repeated within the letter, leaving 40 comments requiring separate responses. Several of these comments have been considered previously but have not yet achieved closure. In addition, about half of EPA's April 2001 comments relate to the subject of the design and administration of the CASWP, while the remainder address issues more properly reserved for consideration during the conduct of the risk assessment. CLH agrees that these two activities are fundamentally linked, and the design of the CAS considered the data use objectives and quality requirements attendant upon and supportive of the risk assessment.

STRUCTURE

The structure of this response-to-comment document is:

- The comments from the EPA's April 20, 2001 letter are included in the exact order and wording throughout the document. Each comment has been numbered sequentially within specific subsections outlined in the letter. This text is presented in *italics*.
- CLH's responses to each comment are included in sequence following each comment in standard text, indented, and following the words "CLH Response:"
- CLH evaluated the comments provided by EPA and NJDEP and found that approximately half are related to the risk assessment, including data analysis and interpretation, *not* to the creel angler survey, which is simply the vehicle to collect the data required for the risk assessment. For clarity and to focus subsequent discussions, comments that relate to the risk assessment and the associated data analysis and interpretation are indicated with an asterisk, as follows: "*CLH Response:"

RESPONSE TO COMMENTS

Section 1 – General Comments

Section 1.1 – Risk Assessment in Superfund

In general, the proposal for the Creel Angler Survey (CAS) fails to address the basic requirements of a Superfund risk assessment. As outlined in the NCP (Preamble page 8710), the goal is to evaluate cancer risks and non-cancer hazards to the Reasonably Maximally Exposed (RME) Individual, and evaluate cancer risks and non-cancer risks under current and future scenarios. Specific examples from the text where this information is lacking are provided below.

CLH Response: EPA mischaracterizes the NCP Preamble as stating that the goal of a Superfund risk assessment is to “evaluate cancer risks and non-cancer hazards to the Reasonably Maximally Exposed (RME) Individual, and evaluate cancer risks and non-cancer hazards under current and future scenarios.” The term “Reasonably Maximally Exposed Individual” does not even appear on the page EPA cites. See 55 Fed. Reg. 8666, 8710 (Mar. 8, 1990). Rather, EPA responds to comments about the “reasonable maximum exposure scenario” on this page, and concludes that “EPA will continue to use the reasonable maximum exposure scenario in risk assessment, although EPA does not believe it necessary to include it as a requirement in the rule” *Id.* If there is a statement of the goal of a risk assessment in the preamble, it is “to determine whether the contaminants of concern identified at the site pose a current or potential risk to human health and the environment in the absence of any remedial action.” *Id.* at 8709. The Creel Angler Survey will provide valuable data for the exposure assessment component of the risk assessment process, consistent with EPA’s preference for basing decisions on site-specific risk assessments. See *id.* at 8709; see also CERCLA § 104 (i) (6) (F).

- 1.1.1. *The CAS Work Plan (CASWP) in Table 1-2 indicates that the consumption rate will be developed based on the average catch and keep rate, average size (by species), trip duration, parts of fish eaten, fraction of weight of parts eaten by respondent, demographics, and season. Application of average rates as indicated in this document, will result in potential underestimates of exposure and is inconsistent with USEPA Superfund guidance which requires evaluation of the risk to an RME individual at the 90th percentile or above. The more appropriate approach is to evaluate the exposures to the RME individual based on the 90th percentile or above (USEPA Exposure Factors Guidelines in 1992 and USEPA, 1989 RAGS -Part A).*

Evaluation of exposures based on averaging is not appropriate; rather the full distribution of the results of the survey should be provided along with information on the specific percentiles of exposure. This information can then be used by EPA to select appropriate points on the distribution for inclusion in the point estimate and the full distribution can be used in a Monte Carlo Analysis (if a Monte Carlo Analysis is performed);

*CLH Response: The CAS will collect information to characterize the full spectrum of results so that probability distributions can be created for Monte Carlo Analysis and for selection of percentiles of the distributions for use in the risk assessment. The average catch and keep rate and average size (by species) referred to in Table 1-2 apply only to a specific angler and the specific trip about which the angler was interviewed, not the full duration of any one angler's or all anglers' exposures.

The On-Site Interview form (Exit Interview Version) that has been used since the commencement of the survey includes space for recording the species of fish/shellfish, the number of each species, and the measurement of each kept fish/shellfish. As shown in the table included on the following page, CLH's CAS, is comparable to, or in most cases exceeds the level of detail contained in other creel angler studies regarding species, numbers, and sizes of fish or crabs collected by other surveys that have been used by EPA to develop default fish consumption rates in the *Exposure Factors Handbook* (Ebert *et al.*, 1993; Connelly *et al.*, 1996; West *et al.*, 1989; West *et al.*, 1993) or to support Superfund risk assessments (e.g., Connelly *et al.*, 1992).

In response to this comment, Table 1-2 in the CASWP will be revised to more fully specify the information collected during the exit interviews that will be used to develop consumption rates.

Table: Comparison of the Passaic River Creel/Angler Survey to Surveys Used to Derive EPA's Default Fish Consumption Rate and New York Survey Used in Hudson River Risk Assessment

Characteristics of Quality Angler Surveys	Surveys Used to Derive EPA's Default Fish Consumption Rate					
	Passaic River Survey	Maine Survey ^a	Lake Ontario Survey ^b	1989 Michigan Survey ^c	1993 Michigan Survey ^d	New York Survey ^e
Pretested	X	X	?	X	X	?
Reviewed by expert panel	X					
On-site interview	X					
Information on licensed and unlicensed anglers	X					
Multilingual	X					
Capture illiterate anglers	X					
Minimal recall burden	X		X	X	X	
Information on fishing activity for entire year	X	X	X			X
Information on fish consumption for entire year	X	X	X		X	
Capture effect of seasonality on fishing activity over entire year	X		X			
Capture effect of seasonality on consumption of fish over a year	X		X		X	
Information on shellfish and fish	X					
Information on night angling	X	?	?	?	?	?
Information on fish consumption specific to waterbody	X			X	X	X
Capture how long angler has fished at a specific waterbody	X					
Able to validate species identification	X					
Measure each fish harvested (e.g., length, weight)	X		X		X	
Composition of fish consumed (i.e., number, species)	X	X	X			
Information on number of meals			X	X	X	X
Portion size model			X	X	X	
Information on preparation/cooking methods	X	X	X	X	X	X
Information on parts consumed by species	X					
Information on fish consumed obtained from other individuals ^f		X				
Demographics of anglers	X	X	X		X	X
Fish consumption information for women of childbearing age	X	X	X	X	X	X
Fish consumption information for pregnant or nursing mothers	X					
Fish consumption information for children	X	X		X		
Information on awareness of advisories	X	X	X	X	X	X
Information on effect of advisory	X	X	X	X	X	X
Established/documented data quality objectives	X	X	?	X	X	?
Met data quality objectives	Pending	X	?		X	?
High respondent participation (> 60%)	X	X				
Information on nonrespondents	X			X		X
Information on anglers at every location fished in the survey area	X					
Information to estimate the size of the exposed population	X					

^a Ebert *et al.* (1993)

^b Connelly *et al.* (1996)

^c West *et al.* (1989)

^d West *et al.* (1993)

^e Connelly *et al.* (1992) used in Hudson River risk assessment

^f Recreationally caught fish from other members of the household or individuals outside of the household.

- 1.1.2. *Past exposure duration in the workplan is based a proportion of the time that the individual has been fishing within the area. Therefore, under the approach outlined in the CASWP, if an individual is 40 years old and has been fishing in the area for 30 years, but has only fished in three of the last five years, the survey would assume 18 years of exposure (i.e., $3/5 \times 30$) duration. So, if an individual started fishing at age 10, the information regarding fishing practices and exposures for the 30 years between ages 10 and 40 would not be fully evaluated in the risk assessment and could underestimate exposure duration (e.g., 18 years vs. 30 years). Considering the goal of protecting current and future exposed populations, it would be more appropriate to evaluate the risks to this individual based on the assumption that they fished every year, except for those years that they specifically stated that they did not. Considering that many of these chemicals are bioaccumulative, it is important to evaluate the activities of the angler based on their lifetime of activity;*

*CLH Response: EPA's comment implies that the CAS assumes exposure durations as stated above; it does not; rather it collects information that can be used in developing exposure duration estimates: starting age for fishing at the Study Area, the number of years fished in the Study Area, and the fraction of the last five years that the angler fished at the Study Area. See the response to Comment 1.1.3 for a discussion of exposure duration estimation methods that can be considered as part of the risk assessment protocol process and the use of CAS data in those methods.

- 1.1.3. *Future exposure duration in the CASWP will be based on the application of a method by Price et al. (1998). This proposed methodology is not the methodology used in the risk assessment for the Hudson River. EPA will provide further comments when it has thoroughly reviewed the Price study;*

*CLH Response: The precise methodology to be used to estimate exposure duration for the risk assessment is a question that will be addressed and resolved in the development of the risk assessment protocols. The purpose of the CAS is to collect information to support the development of exposure factor values for fishing duration. Stated another way, the CAS, like other elements of the ESP, is limited to data collection. Interpretation and analysis of the data to support risk assessment will be accomplished during the conduct of the risk assessment.

The CAS is presently collecting information in a manner that will support use of either the methodology employed in the Hudson River risk assessment or the methodology which is set forth in the referenced Price *et al.* (1998) paper. In particular, the elements from the Survey data that supported development of the fishing duration distribution used for the Hudson River were the angler's age at the time of the survey and the angler's starting age for fishing.

Future fishing duration was predicted from this information. The Price *et al.* (1998) methodology relies on these same pieces of information.

CLH awaits EPA's comments on the Price *et al.* (1998) study.

- 1.1.4. *On page 1-8, the primary concern of the risk assessment are risks and hazards to the RME individual that may include subsistence populations in addition to avid recreational anglers. The full distribution of fish consumption patterns needs to be developed for evaluation before populations are separated out for specific analysis.*

**CLH Response: From the beginning, the CAS has been specifically designed to sample the angler population in a manner that captures the full range of angler behavior and consumption patterns; it also ensures that if subsistence populations are present, they will be included in the data set. All anglers are treated identically during the CAS data collection. Determination of whether subsistence or other potentially sensitive subpopulations are present will occur during the interpretation and analysis of CAS data in the risk assessment.*

Section 1.2 – Consumption Rates

- 1.2.1. *CLH suggests in the CASWP that it will define and determine consumption rates and patterns, based on "trips" and a count of the anglers catch at the end of the day. First, while we agree that a "trip" to fishing sites is required for 1) a catch to happen, and 2) consumption to take place, we do not believe calculating consumption on the basis of "trips" will provide an accurate assessment of consumption, because the angler is not providing sufficiently detailed information on activity patterns.*

While it may be useful to document an angler's catch, we do not believe this "snap shot" in time provides adequate information to calculate quantity and duration of consumption. This information can only be obtained through querying the angler.

Based on this approach, CLH's plan to translate the data into a gram per day ingestion rate remains unclear. From Appendix C, it is unclear how consumption by other members of the angler's family be assessed in the calculation of a gram per day ingestion rate based on the questions presented.

A more accurate assessment of consumption would be derived by developing specific questions to ask the angler. For example:

1. *How often do you go fishing in a year?*
2. *How often, when fishing, do you get a catch?*
3. *What species do you prefer to eat?*
4. *How many years have you eaten fish/crabs caught by you or a member of your family?*
5. *How many fish/crabs do you/family members eat at a meal? (Provide specific portion sizes by family member)*
6. *How many fish/crab meals do you/family members eat a week?*
7. *How many fish/crab meals did you/family members eat in the last month? (Provide specific for each family member)*

While there may be some issues regarding recall bias, we believe this approach will provide better and more accurate information about angler exposure through consumption.

CLH Response: CLH disagrees with EPA that fishing trips do not provide an appropriate basis for accurate assessment of consumption rates. CLH summarizes this comment as consisting of three issues related to CLH's use of the trip basis for collecting data. Following are the three issues and CLH's specific responses:

- 1) *Insufficient information will be collected to provide accurate assessments of consumption, particularly of consumption quantity and duration.*

The CAS as currently administered *does* collect detailed information about anglers' activity patterns that is sufficient for calculating consumption rates. In addition to trip-specific consumption information, the angler is asked about the number of trips taken to the Study Area in the previous month, the number of months of the year he/she fishes in the Study Area, the number of years he/she has fished in the Study Area, actual kept catch data, and whether the angler or anyone else will eat the kept catch. These questions provide a strong foundation for developing the consumption duration and quantity estimates needed for risk assessment.

There is a brief discussion of how consumption rates will be calculated in Section 1.3.2 of the CASWP. More detail is included in a Data Analysis Plan that has been prepared and is currently under review by the Expert Panel that CLH has convened to assist with the CAS design and interpretation. CLH will provide the Data Analysis Plan to EPA once it is finalized to the satisfaction of the Expert Panel.

- 2) *Only information obtained by directly querying the angler can provide information specific enough for these purposes.*

The CAS does collect data by directly querying anglers. Exit interviews have two phases. During the first phase, anglers are queried about their fishing habits and various demographic characteristics. After the angler has finished fishing, the second phase of the interview asks anglers about their day's catch and collects extensive data on any kept catch.

- 3) *It is unclear to EPA how the data being collected can be used to address consumption by the angler's family members.*

Whether or not the people who consume the catch have a familial relationship to the angler is not relevant. The CAS specifically asks anglers with kept catch if they or anyone else will eat the catch. In addition, data are collected on how many of the people who will eat the catch are children, women, and pregnant or nursing mothers.

The Data Analysis Plan also describes how information from anglers will be used to develop consumption rates for non-angler consumers (e.g., other members of the angler's household with whom fish are shared).

CLH disagrees that the series of questions proposed by EPA will result in a more accurate assessment of consumption than the questions currently used in the CAS. The questions suggested by EPA are not specific to location or temporal period. Furthermore, the questions require the angler to estimate usual or typical behavior and to recall quite specific information over significant periods of time, such as number of fishing trips over a year or portion sizes for individuals over a month. These questions impose a difficult estimation task for anglers, who have not previously thought of their average lifetime catch and consumption rates and have a limited time, and probably limited interest to provide an accurate estimate. Several published studies demonstrate the inability that survey respondents have in correctly portraying their behavior when queried in this fashion, especially where positively perceived activities such as fishing are concerned. Examples include Connelly and Brown (1995), Tarrant *et al.* (1993), Thompson and Hubert (1990), Westat, Inc. (1989), Chase and Harada (1984), and Chosh (1978). Focusing on specific events and short-term recall is the generally accepted way to enhance accuracy in survey research (Loewik *et al.*, 1999 and Meredith and Malvestuto, 1996). The methods CLH plans to use to develop the long-term consumption estimates from short-term information, as described in the Data Analysis Plan, have been shown to be more accurate than simple extrapolation of information collected using portion and meal frequency recall (Wilson *et al.*, 2001).

A response to each of the seven questions suggested by EPA is provided below:

1. How often do you go fishing in a year?

This question is not specific to the Study Area, and it is subject to recall bias because the question requires the angler to make a personal estimate of his/her average annual fishing activity. Furthermore, there is no frame of reference to specific seasons, months, or individual preferences, all of which can influence an individual's trip-taking frequency. Instead of asking a question in this form, the CAS collects data on which months anglers have fished and/or crabbed in the past and the number of trips they took in the previous month. Shortening the recall period reduces the amount of recall bias induced by allowing anglers to formulate their estimates over fewer potential trip dates.

2. How often, when fishing, do you get a catch?

This question is not specific to the Study Area, nor does it specify the period over which anglers estimate their catch rate. Is this an annual, seasonal, or lifetime rate? Furthermore, it requires anglers to subjectively recall and estimate their catch rate. Catch rate is a variable that differs by season, location, time of day, tide, etc. This bias is then magnified with trip frequency. As discussed above, the more trips anglers take, the more their catch rate will vary, which will in turn cause a more subjective catch-rate estimate. In contrast, the CAS collects actual creel data for each angler for each day the angler is interviewed. This methodology minimizes estimation burden for the angler.

3. What species do you prefer to eat?

This question is not specific to the Study Area. Moreover, although an angler eats a specific species, he/she may not prefer that species. Therefore, anglers' actual behavior and not their preferences are the relevant basis for exposure calculation. While species preference may drive angling site choice decisions, consumption decisions about specific catch drive exposure levels. For this reason the CAS collects data on each angler's actual creel, whether the angler will eat the creel, and who else will eat the creel.

4. How many years have you eaten fish/crabs caught by you or a member of your family?

This question is not specific to the Study Area. Moreover, fish that are caught outside of the Study Area will not be used in the risk assessment.

5. How many fish/crabs do you/family members eat at a meal? (Provide specific portion sizes by family member)

This question is not specific to the Study Area. It also places a tremendous recall and estimation burden on the angler that is unlikely to be met with accuracy. First, the angler must mentally review all meals eaten by his or her family and determine which included fish or crabs or both. The first accuracy problem occurs because the angler may or may not have been present at all meals eaten by all family members, and may not have information about meals that he or she did not observe. Then, he or she must recall the size of the fish or crab portion eaten at each meal by each person and mentally perform a calculation of the average for each person over the number of meals in the recall period. Given the detailed recall and large number of calculations required, it is probable that the angler's response will not accurately represent the individual's or family's true consumption.

The Passaic River Study Area CAS measures the angler's kept catch and solicits the number of individuals consuming the catch at every on-site interview. These data can be used to calculate portion size for each individual consuming the fish/shellfish kept. Asking the question in this manner greatly reduces the calculation burden placed on the individual, uses data from actual trip behavior, and calculates consumption based on that actual behavior.

6. How many fish/crab meals do you/family members eat a week?

This question is not specific to the Study Area and places similar calculation and estimation burdens on the angler as those described above. Although anglers' estimates of fish/crab meals per week are likely to be more accurate than those for an entire year, actual catch and trip behavior data such as those collected in the CAS are still preferable since this estimation method minimizes recall bias.

*7. How many fish/crab meals did you/family members eat in the last month?
(Provide specific for each family member)*

This question is not specific to the Study Area and places on the angler calculation and estimation burdens similar to those described above. Anglers' estimates of fish/crab meals per month are likely to be more accurate than those for an entire year but less accurate than those for a week. Again, actual catch and trip behavior data such as those collected in the CAS are preferable in order to minimize recall bias.

In summary, the addition of these questions would increase the recall and calculation burden placed on the angler and increase the length of the on-site interview. The July 2000 pretest results indicated anglers wanted as short an interview as possible. Based on the pretest results, we believe the questionnaire design properly balances data requirements with interviewee preferences for interview duration and question type. Therefore, lengthening the interview questionnaire would only serve to lower participation rates.

A survey must be tailored to maximize accurate data collection subject to bias minimization, size of the exposed population, and available modeling technology. Based on the pretest results, we believe that our method of data collection meets these requirements. Our approach minimizes bias by maximizing the amount of actual, or "real-time" data collected.

The approach used by CLH has been validated by the Expert Panel convened by CLH in lieu of EPA's participation in this collection of essential, site-specific data for the Passaic River Study Area

Section 1.3 – Modeling / Portion-Size

- 1.3.1. It is unclear from the work plan exactly how CLH plans to determine portion size. On the one hand, there is reference to a "portion-size approach model for several portion sizes" (p. 1-12) yet there is no information on the survey form itself that indicates that such models will be used in conversation with the interviewee (Appendix C). In other studies of consumption, interviewers asked anglers what participants ate and how much they ate at the time of the interview. Visual aids were used to help the angler more accurately estimate how big a portion he/she ate at a particular meal.*

CLH Response: During the early stages of the development of the CAS, there were plans to include portion-size models for estimating consumption rates in addition to a fish-measurement approach. This dual approach was used in the

Santa Monica Bay Seafood Consumption Study (Southern California Coastal Water Research Project (SCCWRP) and MBC Applied Environmental Sciences (MBC), 1994). However, these plans were abandoned in favor of a singular focus on the fish measurement method when it was determined based on pretest results that a short, straightforward interview was required to gain angler cooperation. Furthermore, fish measurement methods are more accurate than portion size recall for determining per-trip consumption. Data forms from the *Santa Monica Bay Seafood Consumption Study* showed that anglers had difficulty matching portion size models to the fish they had in hand, often overpredicting the portions that could be provided by the fish they had creeled (Deposition of I. Winstanley, CV 90 3122-AAH (JRx), Volume II, 1999, pp. 336-43 and 350-355).

In response to this comment, the work plan will be modified to remove references to portion size models, thereby accurately representing the CAS's focus on fish-measurement methods.

- 1.3.2. *On the other hand, if these models will not be used on a person by person basis to estimate portion size, but calculated by some other mechanism, that is less appropriate. The use of extrapolation models based on assumptions is a helpful tool when you do not have the opportunity to talk with the study subject. In this case, there will be that opportunity. Therefore, time should be spent on getting this information directly from the angler, rather than through the use of mathematical or extrapolation models. The research should not predetermine and define what a portion is before this information is obtained from the angler. Such an approach for determining portion size will likely underestimate exposure/risk.*

CLH Response: First because of the tremendous recall, calculation, and prediction burden, it is impossible to directly and accurately obtain from an angler a consumption rate in g/day that represents average daily consumption from the site over the time period during which the angler eats fish from the site. Because this information is not directly available, *all* exposure assessment methods, and consumption estimation methods in particular, require extrapolation models and assumptions.

The approach used in most surveys that include portion-size models is to ask the angler to describe portion size for each consumer with reference to a single portion-size model. The size of this model (i.e., the portion it represents) is necessarily predetermined. Anglers typically are asked to describe how much they eat as a fraction of the size of the model. Anglers generally round these responses to multiples or halves of the portion size. Thus, the portion-size model method is a crude method for estimating consumption and is highly dependent on the size of the model taken into the

field. Further, as mentioned above, in the *Santa Monica Bay Seafood Consumption Study*, anglers had difficulty matching portion size models to the fish they had in hand, often overpredicting the portions that could be provided by the fish they had creeled. The alternative used in this CAS of measuring fish and calculating edible weights based on length-weight relationships from site-specific data and the literature eliminates the guesswork on the part of the angler.

- 1.3.3. *There is also a great deal of discussion in the work plan about using modeling to calculate the exposure of this population. The modeling, as described in this work plan, and applied in this case, will underestimate exposure in this population. This survey project provides the opportunity to collect real time information. Actual estimates of consumption rates, residency questions, sociodemographic influences, etc. can all be explored as part of the survey work.*

While modeling can be useful when information is lacking: it seems unnecessary here, when actual data from the exposed population can be collected.

CLH Response: EPA asserts three points in this comment:

- 1) *CLH's model will underestimate exposure.*

Without *a priori* knowledge of the actual exposure levels in the population, it is impossible to presume that one method or another will necessarily underestimate or overestimate exposure. CLH has designed the CAS to collect the information to support the most realistic and accurate exposure assessment possible for lower Passaic River anglers. Numerous decisions will be made in the analysis of the CAS and other data to support the risk assessment that will influence the degree of conservatism in the final risk estimates.

- 2) *"Real time" information should be collected as part of the CAS.*

The CAS does, in fact, collect real time data from anglers. The survey asks in what months the anglers fish and/or crab, how many times they fished and/or crabbed in the last month, whether they fish or crab or sometimes fish and sometimes crab, how many fish/shellfish they caught that day, how many fish/shellfish they kept that day, whether they will eat the fish/shellfish that they caught that day, who else will eat any of the fish/shellfish caught that day, and many other types of questions to collect actual data on angler behavior.

3) Modeling is unnecessary when actual data are collected.

As discussed above, *all* exposure assessment methods, and consumption estimation methods in particular, require extrapolation models and assumptions. The only way to avoid modeling and assumptions in exposure assessment would be to ask anglers the obviously unanswerable question, "To what average daily dose of chemicals are you exposed based on your contact with the Passaic River Study Area?"

The methodology proposed by EPA for calculating exposure uses reported behavior by anglers over the exposure period. Use of these data to estimate exposure requires the use of a linear model that assumes that consumption, trip, portion, and other reported data remain constant over the duration of the individual's exposure. This is a highly simplistic model. In contrast, the method proposed by CLH employs information obtained on individual trips to calculate exposure. In addition to minimizing recall bias, this method collects the full variation of angler data over all observed trips. From these data it is possible to calculate estimates using typical behavior. However, the additional data allow the development of a more realistic model where the angler's consumption, trip, and other behavior vary over time within the reported ranges and where data can be weighted to reflect the relative probabilities of each observation. Such a model allows the calculations to account for variations in angler behavior, such as increased trip frequency in summer months.

Section 1.4 – Population

- 1.4.1. *Considerable discussion is presented throughout the work plan regarding population size. It is important to realize that in risk assessment, EPA regulations and guidance require evaluation of cancer risks and non-cancer hazards to the RME and Central Tendency (average) Individual and does not calculate population risks.*

*CLH Response: On the contrary, numerous EPA guidance documents discuss the importance of population risk (see below: USEPA 1997, 1992, 1989). Estimation of population risk is a critical component of risk characterization and, pursuant to EPA guidance, it will be addressed in the Human and Ecological Risk Assessment (HERA). Population risk is typically estimated by multiplying the individual risk by the size of the potentially exposed population. It yields an expected increase in the number of adverse health effects for a given population size. For the HERA, it will serve as an important metric because it will provide the interested parties (the public, the Agency, and the respondent) with an understanding of the overall risk to the

fish consuming and general population. It also provides a measurement endpoint that can be evaluated by an epidemiological analysis.

Numerous USEPA guidance documents specifically mention calculation of population risk. For example, the USEPA 1989 Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual, states:

“...if the size of the potentially exposed population is large, the presentation of the population numbers may be of assistance to the RPM, especially in evaluating risks in the context of current land use” (p. 8-26).

As stated in the USEPA 1992 Guidance on Risk Characterization for Risk Managers and Risk Assessors:

“EPA risk assessments will be expected to address or provide descriptions of population risk” (p. 21).

“Regarding exposure and risk characterization, it is Agency policy to present information on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (i.e., central tendency, high end of individual risk, *population risk*, important subgroups if known)...”. “*This guidance applies to all Agency offices.*” (p. 5, italics added).

Finally, and of greatest relevance and importance, the USEPA 1997 Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories gives detailed and explicit guidance on methods for calculating population risk for cancer and noncancer effects:

“2.5.1 Carcinogenic Toxicity

Population Risk

The estimated population cancer risk is calculated by multiplying the number of people in an exposure group (with the same exposure) by the lifetime cancer risks calculated from the equation above. The population risk equation is:

$$(\text{population cancer risk}) = \text{lifetime risk} \times (\text{size of exposed population})$$

For example, if 5,000 people are exposed at a risk level of one per thousand (1×10^{-3}) (per lifetime), the overall risk to that population is five additional cancer cases ($5,000 \times 1 \times 10^{-3} = 5$) over the background level.” (p. 2-60)

“2.5.2 Noncarcinogenic Toxicity

Population Risk

The population risk is expressed as the number of individuals with exposure levels greater than the RfD:

Noncarcinogenic risk = population with exposure greater than the RfD” (p. 2-62).

For the sake of brevity, we have not listed all the excerpts from all the EPA guidance documents that discuss the importance of population risk. However, it is clear that EPA Superfund guidance, guidance for risk managers, and guidance specific to fish consumption risk assessments recommend the evaluation of population risk.

Section 1.5 – Exposure Time Frame

- 1.5.1. *NJDEP's study of the Newark Bay Complex found the preponderance of anglers reporting that they had lived in the area for their entire lives. It would be useful in this study, to ask a similar question and to follow it with a question about how long the angler has eaten fish and crabs from the Study Area. If this is done, then estimates extrapolated from the literature will not be necessary to determine the exposure duration. Real time data can be used in the risk calculation for the exposure duration. Again, estimates, models and literature based data is useful when actual, site-specific data is unavailable. In this case, data can be obtained from the anglers directly.*

CLH Response: Data regarding exposure duration are being collected directly from anglers in the current implementation of the CAS. As discussed in the response to Comment 1.1.3 above, the CAS is presently collecting information in a manner that will support either the methodology used for exposure duration for the Hudson River risk assessment or that set forth in the Price *et al* (1998) paper and will allow modifications for interruptions in years fished. Extrapolations from the literature will not be necessary.

Section 1.6 – Counting

- 1.6.1. *The purpose of counting individuals in the survey remains unclear. On page 1-4, the document indicates that there is limited boating activity and boat-based angling is not expected to be a key component of this CAS. On page 3-2 and 3-3, the CAS*

indicates that the counting will provide an estimate of the population and allows for potential intercept of every angler identified on the river. However, the CAS also indicates that the counting and existence of anglers in boats are not the basis for intercepting individuals. Instead the plan is to use some statistical random method of selecting anglers for interview.

A more appropriate approach would be to include more intercept teams so that all anglers identified, whether on boat or on land, are interviewed.

These statements raise the following concerns: 1. As stated above, the Superfund program is based on evaluating risks to the RME and CT individual and not a population. Without a specific explanation regarding the planned use of counts, EPA cannot comment on whether this approach is appropriate. 2. It sounds as if, there is a high probability that the lower half of the Study Area will not be evaluated, thus reducing the study area by a significant area, i.e., almost half.

CLH Response: There are two primary purposes for counting anglers in the Study Area:

1. To provide a detailed account of all the locations where anglers fish and/or crab in the Study Area and
2. To provide the basis for estimating the level of activity at every point along the Study Area shoreline.

The On-Site Counts are necessary because the number, location, and relative activity at all access points are not known *a priori*. Results from the On-Site Counts will indicate the location and frequency of angling activity at every point within the Study Area. It is important to recognize that the boat-based, On-Site Counts are not boat-based because of the limited boating activity, but rather because observation by boat ensures that every angler fishing and/or crabbing in the Study Area is enumerated.

The suggestion that CLH will use some statistical random method to select anglers for interview is incorrect. The random selection process is for the location of the on-site interview team on a given shift. Once the interview site is selected and the interview team is located at the site, the interviewers attempt to interview every angler, not a random sampling of anglers.

Based on this EPA comment, it is apparent that there is confusion regarding the term "random." The term random in the CASWP is a statistical term that refers to the nature of the selection process. Random does not mean arbitrary. It means that the elements in the population (e.g., days selected for counting and interviewing out of all the days in the year) are selected in such a way that every set of elements in the population has an equal probability of being

selected. This is the case of the simple random sample. Because supplemental information is available to aid the CAS sample design, we use a stratified random sample. For example, we know that anglers are likely to fish more in the summer than in the winter simply because of the warmer temperatures in the summer. Therefore, we concentrate more of our efforts on collecting summer observations than winter observations. However, our selection process within strata (e.g., season) is still random; that is, the set of days selected for counting and interviewing out of the total set of winter days has an equal probability of being selected.

For selecting the location for a given day of interviewing, we also have supplemental information we can use to select that site. The On-Site Counts provide information regarding all the locations where anglers are fishing and/or crabbing and the frequency and level of activity at each one of those locations. Because we want to maximize the probability of interviewing anglers, we sample more heavily at those locations with higher amounts of angling activity. The On-Site Counts provide the basis for the amount of angling activity.

Weights for the random selection of interview locations are based on prior months' counts of anglers at each site determined by the boat-based count team. Therefore, sites with more angling activity will be more heavily weighted than those with less activity and the interview team will be sent to these sites more often. Weighting towards the most heavily used sites maximizes angler contact, thus maximizing the amount of interview data collected. To ensure complete coverage of the Study Area, regardless of activity, no public access site will be removed from the list of possible interview sites. If the amount of fishing/crabbing activity at any of the sites changes over the course of the study period, the weights for the random selection process will be altered to reflect that changed activity (CASWP, Section 4.4). Moreover, if the angler counts reveal a frequently used site that is not a current interview site, then that site will be added to the list of interview locations. It will then be randomly sampled along with the original interview locations.

With respect to point 1 in the last paragraph of the comment, the data collected by the CAS will allow for evaluation of risks to the RME and CT individual. A more detailed explanation of the planned use of the counts is found in the Data Analysis Plan.

With respect to point 2, this comment is mistaken. The boat-based count team travels from the northern boundary of the Study Area to the southern boundary of the Study Area enumerating every angler seen on the River. Upon reaching the southern boundary, the team turns around and returns to the northern boundary, again enumerating all anglers seen on the River. The boat-based team repeats this pattern throughout the entire shift (see Section

3.1 of the CASWP). Therefore, every section of the Study Area is evaluated; no section is missed. As explained above, if anglers are observed with frequency at a point other than the five predetermined exit-interview locations, that location will be added to the list of interview locations. It will then be randomly sampled along with the original interview locations to assign interview shifts to the locations (CASWP, Section 4.4).

- 1.6.2. *In addition, incorporating the boat count information relating to race and ethnicity of individuals does not provide the level of detail sought for the study as a whole. The characterization of an individual counted on the shore by boat is limited to "white" or "non-white." While this recognizes the difficulty of determining ethnicity from a distance, the imprecision also can lead to misclassifications. Based on papers by Kirk Pflugh et al. (1999) and Burger et al. (1999), there are significant differences among the white, Latino, and black angling communities in the Study Area and adjacent areas. By designating an angler as only "white" or "non-white" and attempting to overlay this information onto interview data with more specific ethnic identification, it could minimize these distinctions and underestimate consumption. The only appropriate manner for conducting these surveys is by asking individuals to self-identify their identity.*

CLH Response: First, despite numerous requests to EPA (May 23, 2000 Meeting; October 4, 2000 Meeting, October 6, 2000 Letter, and October 26, 2000 Letter), CLH still awaits data to show that the Passaic River Study Area was included in the study underlying the Kirk Phlugh *et al.* (1999) and Burger *et al.* (1999) papers; until such confirmatory data are received, CLH will continue to rely on statements made by Ms. Kirk Phlugh in 1995 that no sampling locations were in the Study Area. Given this history, the applicability of these studies to the Study Area remains in question.

CLH recognizes that ethnic identification via observation, especially from a boat, is likely to be imprecise. As a result, links between specific consumption rates and ethnicity that may be included in the risk assessment will be based on exit interview information only, where anglers self-report their ethnicity. It should be noted, however, that there is no clear scientific support for EPA's assertion in this comment that minimizing ethnic distinctions could underestimate consumption rates, especially in settings where the concern is consumption of self-caught fish. Many studies have failed to statistically distinguish distributions of consumption rates of self-caught fish on the basis of ethnicity (e.g., Ebert *et al.*, 1993; Allen *et al.*, 1996). The evidence supporting an influence of ethnicity on rates of consumption of self-caught fish is generally limited to areas where ethnic communities are rather isolated, such as Native Americans living on reservations.

The ethnicity data gathered in on-site counts will only be used in conjunction with the on-site interview ethnicity data for sites where interviews are not taking place on a given day. When an interview team is present at a site, the count team will relay to the interview team the number and position of anglers at the site. The interview team will then interview these anglers. During the interview the anglers will self-identify their ethnicity. In the case that the angler will not participate in an interview, the interviewer will complete a Missed Creel Report form. While the angler will not self-identify his/her ethnicity, the proximity of the interviewer will allow for more accuracy in assigning the angler's ethnicity than is available to the count team.

The pretest results show that anglers do not like to be approached by boats for several reasons (CASWP, Section 3.1.1.). Obviously, if these anglers are not interviewed, they cannot self-identify their ethnicity to the count team. The On-Site Count Protocol explains that the counters should differentiate between white and non-white and, if possible, write the race in the blank if non-white. The counters must use their best judgment to determine race for non-white individuals. If race cannot be determined, the counters will leave empty the blank next to "non-white" (CASWP, Section 3.1.8). CLH decided that the benefits of collecting more reliable information, with potentially less detail, exceed those of collecting unreliable information.

Section 1. 7 – Interviewing

1.7.1. The work plan also describes a stratified random sample to select who will be interviewed and where. CLH suggests that there are only five fishing locations in the Study Area and that they will randomly select which sites to visit on any given interview day. This random methodology appears to be unnecessary. Because the target audience and fishing sites may be limited in size, the goal of the effort should not be to randomly select from within this population, but rather to more accurately characterize this population by interviewing all anglers seen fishing in the Study Area. Randomly selecting who will be interviewed and where seems to be setting up a process that will underestimate the actual number of anglers and possibly consumers in the Study Area.

A more accurate approach is to travel daily to all the sites and look for other sites beyond the pre-selected five sites, so that a more accurate representation of this affected group can be obtained. Additionally, CLH suggests that the Study Area has limited access because of private property and industry. While some parts of the river are private property and industrial, others are simply not, and are easily accessible (e.g., the network of waterfront parks in Harrison and Kearny). Furthermore, during NJDEP's previous survey work, which included this Study Area, NJDEP personnel observed that during meal breaks at the industrial points,

workers did come down to the river to fish and crab. If attempts are not made to reach these people as well, an accurate calculation of exposure will not be developed.

CLH Response: This comment is incorrect. CLH has designed a random sampling protocol to select the location where interviews will take place on a given interview day. Once the interview team is at that location, the interviewers attempt to interview every potential respondent (i.e., anyone angling or collecting fish and/or crabs from anglers). The random sample is weighted according to the previous month's count results (CASWP, Section 4.4).

CLH does not suggest that there are only five fishing locations in the Study Area but rather that the Study Area contains a small number of specific, identifiable public-access points for fishing and or crabbing (CASWP, Section 3.0). As previously indicated, one of the primary purposes of the On-Site Counts is to enumerate all anglers at all locations in the Study Area. Based on previous observation, the public-access points in the Study Area represent the points with the greatest angling activity (CASWP, Section 4.1). On-Site Count data collected to date support these previous observations.

Again, it is apparent that there is confusion regarding the term random. The term random in the CASWP is a statistical term that refers to the nature of the selection process. Random does not mean arbitrary. It means that the elements in the population (e.g., days selected for counting and interviewing out of all the days in the year) are being selected in such a way that every set of elements in the population has an equal probability of being selected (this explanation is illustrative only and pertains to the simple random sample). Currently, the five interview locations are Riverbank Park Kearny, Pathmark Bulkhead, Hess Gas Station, Heliport, and Riverbank Park Ironbound (CASWP, Locations 2-6 on Figure 3-1). The random sampling process only selects the interview location. The On-Site Interview protocol in Section 3.2.3 of the CASWP states that the interview team will attempt to interview every angler who visits the selected site. If an angler refuses to participate in an interview, the interview team will complete a Missed Creel Report for the angler to collect as much catch and demographic information on the angler as possible. The On-Site Interview protocol guarantees that data will be collected on all anglers who visit the selected site.

The boat-based team is traveling throughout the entire Study Area looking for any sites in addition to the five publicly accessible sites. CLH reiterates that the Study Area has limited access because of private property and industry (based on an evaluation of aerial photography of the 6 mile Study Area, approximately 8½% is available for public access). Moreover, as stated in Section 3.1.2 of the CASWP, the network of waterfront parks in Harrison and

Kearny are included in the initial list of angling sites (i.e., Riverbank Park-Kearny: CASWP, Figure 3-1).

To date, the boat-based count team has not observed any workers fishing or crabbing at the industrial points. If anglers are observed fishing or crabbing on private property, CLH will attempt to gain access to the property in order to interview these anglers. Because CLH will not trespass on private property, if access is denied or no one is available to grant access, CLH will be unable to interview on that private property (CASWP, Section 4.4). If access cannot be obtained, the boat-based count team will continue to enumerate these anglers with the Angler/Crabber Counts form.

- 1.7.2. *If anglers are seen on private property on a number of occasions, CLH should make an attempt to gain access to that private [sic], despite the extra steps it may take to do so.*

CLH Response: This potential occurrence is already addressed in the CASWP: "If the angler counts reveal a frequently used site that is not a current interview site, then that site will be added to the list of interview locations. It will then be randomly sampled along with the original interview locations. If the angler counts reveal infrequently used, non-interview sites, demographic information from the counts (i.e., approximate age, race, and gender of anglers) will be combined with the interview data for the risk assessment. If the counts reveal fishing/crabbing activity on private property, those observations will be treated the same as the observations from infrequently used, non-interview sites." (CASWP, Section 4.4) Once the boat-based counts identify private-property angling on a number of occasions, CLH will seek access to the private property. This example illustrates the importance and benefits of the boat-based counts, for they enumerate all anglers at all potential Study Area locations.

- 1.7.3. *Finally, in describing the process it will use to interview anglers, CLH describes reinterviewing anglers if they are observed in the field again. We recommend against this. First, it does not add to the database on the number of users in the Study Area, and it does not provide additional information on consumption patterns from within this group. If this information is asked and answered the first time as suggested above, there is no value to a reinterview. However, if the goal of the reinterview is to document how often people catch and keep, CLH can accomplish this through participant observation. This will work if CLH intends to use the same interviewers for the same sites throughout the course of the study, which we*

recommend. This will allow the interviewer to become familiar with the site and the people, and would eliminate the need to reinterview.

CLH Response: CLH disagrees with EPA's opinion that there is no value to reinterviews in the CAS. CLH's position is related in part to CLH's disagreement with EPA regarding the types of questions and recall periods to be used in the CAS, as discussed in response to comment 1.2.1. The reinterviews are useful for collecting additional information on trip-taking frequency and trip-specific catch and consumption that are subject to variation due to species availability or seasons of the year. This information is very valuable for understanding consumption patterns among Study Area anglers. Using observation only to determine catch and keep rates, as is done via the Missed Creel Report forms, has some value but does not provide as much detailed information as is available via a completed interview.

Using the same interviewers at the same sites throughout the course of the study has its trade-offs. Keeping the same interviewers at the same interview sites may increase the longitudinal response rate by building rapport between interviewers and respondents. However, systematically assigning interview teams across interview sites could suppress participation rates among certain anglers. Certain anglers may decrease their participation because they dislike the interview team at the site, an effect that can be statistically determined but not adjusted. The reality of the survey administration is that multiple interview teams are required because the survey is one year long. The vast majority of angling activity in the Study Area takes place at the Hess Gas Station, so most of the on-site interview effort has been directed at this location. Each interview team will be scheduled to interview there at some time during the survey period. Therefore, given the logistical constraints of survey administration and the bias trade-off, no specific logistical designs regarding interview team placement will be incorporated into the CAS.

Section 1.8 –Future Consumption

- 1.8.1. *It is not clear from the work plan how CLH will take into account the storage/freezing of fish/crabs for either the survey or in the model. Future consumption of frozen fish and crabs must be addressed in the exposure assessment to be consistent with the plans for evaluating current and future cancer risks and non-cancer hazards in the baseline risk assessment.*

CLH Response: As explained in Section 1.3.2.1 of the CASWP, measuring exposure in reference to trips does not limit consumption to the day of the trip. Unless fish or crabs are harvested on a successful trip, they cannot be

consumed in the future. Whether the fish or crabs were consumed fresh on the day of the trip or following a period of storage or freezing, the total amount of fish consumed from that trip is accounted for when measuring consumption in reference to the trip.

Section 1.9 –Pregnant Individuals, Women of Child Bearing Age, Infants, and Minors

- 1.9.1. *The early sections of the report (page 1-7) indicate that pregnant individuals, women of childbearing age, infants exposed to contaminants in breast milk, and young children will be evaluated in the risk assessment. However, in the Pathways Analysis Report the document indicates that the adult will serve as a surrogate for these individuals and in this report page 1-9, the report indicates that a "hypothetical angler" will be evaluated in the assessment. EPA does not agree that it is appropriate to use the adult as surrogate for these other categories. Questions in Appendix C will not provide specific information on the amount of fish consumed by these sensitive populations for inclusion in the risk calculations. These inconsistencies are of major concern, since a potentially sensitive population will be excluded from the analysis.*

While we recognize the potential limitations of modeling chemical exposures to a fetus and to a nursing infant through breast milk, it is possible to evaluate ingestion of fish by infants, young children and women of child bearing age, and they must be included in the assessment. It is unclear how the survey question relating to pregnant and nursing women, generally, will be translated to a specific dose to the fetus or child. Moreover, by asking, generally, whether fish is provided to a child under 15, without evaluating portion size, the survey fails to assess the doses to which these individual populations will be exposed, across the range of ages from infant to 15. In addition, because no anglers younger than 18 will be interviewed, the risk to anglers between the age of 15 and 18 cannot be evaluated.

*CLH Response: In our previous discussions with Region 2 staff, and elsewhere in EPA's comments, EPA suggested that the risk assessment prepared by Region 2 for the Hudson River would serve as a useful template for the HERA. While we disagree with the possible implication that the Hudson River risk assessment is a useful template for the Passaic HERA, CLH notes that Region 2 did not evaluate pregnant women, nursing infants, or minors in their assessment of the potentially exposed populations in the Hudson River, and there does not appear to be any discussion as to why these populations were not considered. Yet the above comment suggests that these populations must be considered in the HERA. This inconsistency suggests that either Region 2's Hudson River risk assessment did not evaluate all potentially exposed populations, or that the Agency is creating a higher standard for the HERA than it established for itself. CLH requests

clarification as to why the Agency requires the HERA to include these populations.

As a point of clarification, the assessment of doses to any exposed persons will not occur in the CAS; rather, the CAS collects data to support the risk assessment where dose calculations will be performed. The questions regarding whether children under 15, women of childbearing age, or pregnant or nursing women are consumers of the angler's catch are included in the CAS to collect data on whether these potentially sensitive subpopulations are exposed to fish or crabs from the Passaic River Study Area. Anglers younger than 18 are not interviewed for legal/liability reasons; however, if angling youth are observed by the interview team, then a missed creel report is completed by the interview team to document the observation. The response to comment 3.8 summarizes the intended methods for determining portion sizes that apply to all identified consumers.

Section 1.10 – Subsistence Angler

- 1.10.1. *The document indicates that the subsistence angler will be evaluated separately. This a priori determination is not appropriate since it does not give the assessor information on the full range of exposures. A full distribution of the data from the Creel Survey should be included in the assessment so that the risk assessor can fully understand the full range of ingestion patterns. This analysis is necessary before subsistence anglers are separated as a separate population.*

*CLH Response: This response is the same as for Comment 1.1.4 above. From the beginning, the CAS has been specifically designed to sample the angler population in a manner that captures the full range of angler behavior and consumption patterns and also ensures that if subsistence populations are present, they will be included in the data set. All anglers are treated identically during the CAS data collection. The determination of whether subsistence or other potentially sensitive subpopulations are present will occur during the interpretation and analysis of CAS data in the risk assessment.

Section 1.11 – Event-by-Event Analysis

- 1.11.1. *In the event that a Monte Carlo Analysis work plan is submitted and approved by the Agency, it should follow the peer-reviewed approach used on the Hudson River site.*

The CAS indicates that the Monte Carlo Analysis will be based on an event-by-event analysis similar to the Hudson River PCB Superfund site risk assessment. As a point of clarification, the event by event analysis approach proposed by CLH here is similar to that proposed to the Agency by the Responsible Party for the Hudson River study in the early stages of the risk assessment and it was rejected based on the potential to underestimate cancer risks and non-cancer hazards for the angling population.

*CLH Response: The Hudson River risk assessment may in some limited respects serve as a useful reference for the HERA. However, it is anticipated that more site-specific data will be available to support the HERA than were available for the Hudson River site and that the data will be more detailed. Further, in the passage of time since the Hudson River risk assessment work plan was developed (1998), there have been advances in the literature and publication of additional EPA guidance, including Guidance for Conducting Fish and Wildlife Consumption Surveys (1998), Sociodemographic Data used for Identifying Potentially Highly Exposed Populations (1999), and Risk Assessment Guidance for Superfund: Volume 3 (Part A, Process for Conducting Probabilistic Risk Assessment) (1999 Draft). The site uses and site conditions also differ between the Hudson River and the Passaic River Study Area. Consequently, the scope of the upcoming HERA should not be limited to that covered by the Hudson River risk assessment.

The point of the statement regarding event-by-event analysis and the Hudson River risk assessment in the CASWP is that the concept of an event-by-event approach is not novel in Superfund risk assessment. However, the event-by-event approach employed for the fish consumption pathway in the Hudson River risk assessment was limited to annual changes in a few exposure factor values and did not have the benefit of site-specific data. Data from the CAS will be detailed enough to support a smaller time increment for changes in exposure factor values related to fish consumption than was possible for the Hudson River risk assessment and will be specific to the Passaic River Study Area.

The matter of risk assessment methodology is one to be resolved in the risk assessment protocol process. As discussions proceed regarding protocols for the Passaic HERA, CLH fully expects EPA to fairly consider its proposals and the support for them. EPA should not reject CLH proposals regarding risk assessment issues simply on the grounds that the Hudson River risk assessment did not approach issues in the same way.

- 1.11.2. *It also appears from page 1-9 that the exposure assessment will only simulate the exposures of a hypothetical angler without accounting for sharing of fish, etc. This approach will not address risks to non-angling populations i.e., children, infants, adults, etc.*

*CLH Response: The CAS is designed to target anglers because they are the source of any fish and/or crabs consumed from the Study Area. Indeed, they are the only source because the area does not support any commercial fishery. Anglers who catch fish and/or crabs in the Study Area may share their catch with other individuals such as family members and friends. Thus, individuals other than anglers also may be exposed to chemicals in fish harvested from the Study Area. However, efficiently and accurately collecting information on both angler and non-angler consumers is difficult. The CAS attempts to gather as much information as possible on non-angler consumption by asking anglers with whom they will share their kept catch and whether any of the non-angler consumers are members of potentially sensitive subpopulations such as children, women, and pregnant or nursing women. The CAS also collects information on non-angler consumption by asking anglers whether they've given away any fish. Exit-interview procedures specify that the interviewer will attempt to interview any person at the interview site who has fishing equipment and/or fish, crabs, or eel (CASPM, Section 3.1.2). Therefore, if the angler has given away fish or crabs while at the interview site, the interviewer will attempt to interview the recipient of such fish or crabs, providing further data on non-angler consumption.

Most studies of fish consumption used in risk assessment applications concentrate on collecting complete and accurate information that can be used to estimate anglers' exposures (e.g., Wilson *et al.*, 1999; SCCWRP and MBC, 1994; Bales, 1993; Ebert *et al.*, 1993). The lack of direct information from non-angler consumers on their consumption practices prevents estimating their exposures and risks with the same precision that is possible for anglers. In general, however, the results of an analysis of angler exposures and associated risks represent a reasonable and conservative measure of the exposures and risk to non-angler consumers.

Section 1.12 – Cooking Losses

- 1.12.1. *The CAS expends considerable effort on collecting data on cooking practices with the expectation that the information on the cooking practices will enable the risk assessor to reduce the exposure point concentration in fish and crab. As discussed in the Hudson River risk assessment, experimental results range considerably, both between various cooking methods and within the same method. Most PCB losses (expressed as percent of Total PCB mass before and after cooking) were between*

10 and 40%. Losses as high as 74% were reported in one study while net gains of PCBs were reported in several other studies. The extent of PCB cooking losses has not been well characterized in the published literature for PCBs and other chemicals, and quantitative cooking losses remain uncertain. The chemical losses/gains may be a function of the cooking method (i.e., baking, frying, broiling, etc.), the cooking duration, the temperature during cooking, preparation techniques (trimming or not trimming), the lipid content of the fish, the fish species, the magnitude of the chemical contamination in the raw fish, the reporting methods and/or the homologues present in the fish, and the techniques used for extracting and measuring PCBs or other chemicals, are another factor that could contribute to the observed differences in cooking loss between study.

In this study, considerable information is being collected regarding fish cooking practices for fish and crabs, however, as noted above, there is considerable uncertainty regarding the effects of cooking on concentrations in fish for a variety of chemicals and cooking methods. The work plan fails to address how the data on the cooking practices will be combined with the existing literature on concentrations in fish to estimate the final concentration to which the individual is exposed. Further, the reference provided only addresses concentrations of DDT and PCBs while another major chemical of concern is dioxin, which is not described in this article. The report fails to consider that the risk assessment will be evaluating more than one chemical of concern and studies of the impacts of cooking with multiple contaminants in the fish are limited or non-existent. Greater detail on this method for evaluating cooking losses in the analysis will be necessary to determine the feasibility of combining the concentration data with the variety of fish cooking practices identified in the survey.

*CLH Response: EPA's presumption that CLH's motives for collecting cooking method data are limited to enabling reduction of exposure point concentrations is irresponsible. The CAS includes questions on cooking methods to collect from anglers the relevant site-specific information on this exposure factor. The attached Table 1 demonstrates that cooking method questions are a common feature of such studies. How the risk assessment will combine CAS information with other relevant information to address cooking losses is a matter for the risk assessment protocol process.

Section 1.13 – Data Submittal to EPA

- 1.13.1. To review the results of the CAS and evaluate its utility in the risk assessment, CLH must submit copies of the raw paper data (e.g., counting sheets, exit interview, missed creel reports), raw electronic data (the STATA data base system), and summary statistical information in electronic and paper form, as well as definitions used in the data base systems. All supporting information should also be included.

Upon receipt and review of this information, EPA may determine that additional information is necessary and will request it at that time.

CLH Response: Consistent with CLH's policy of providing all data to the Agency, whether collected under the Administrative Order on Consent or under a private-scope project, CLH will provide to USEPA all of the data collected during conduct of the CAS.

Section 2 – Specific Comments

Section 2.1 – Comments Specific to the Letter Dated October 24, 2000

- 2.1.1. *The brief description presented regarding the expert panel does not provide adequate information. The goals / purposes of this "expert panel" need to be defined along with the selection process for these experts. As previously mentioned in my November 17, 2000 letter, EPA has developed peer-review guidance. This guidance outlines the requirements for an independent peer review panel, identifies procedures for establishing questions and issues to be addressed by the panel, describes the decision process, the scope of the panel, the manner in which panel deliberations are to be conducted and documented, addresses opening the process to the public, and potential conflicts of interest. It is unclear from the current document how the proposed peer-review will address these issues nor the procedure that was used in selecting the experts.*

CLH Response: CLH is very familiar with the EPA guidance on convening expert panels: USEPA's Peer Review Handbook (2000). The independent third party that organized the panel, Association for Environmental Health and Sciences (AEHS), is knowledgeable of the contents of the 1998 version of the document, and when a revised version was released in 2000, CLH reviewed it to ensure that the process followed was consistent with the revised guidance. CLH would be pleased to forward to EPA, in a separate submittal, additional detail regarding the formation of the panel and its charge, with specific reference to the guidance and a description of how the panel's activities comport with that guidance. CLH Project Team members that have previous experience with EPA Expert Panels note that the procedure utilized by CLH with regard to the expert panel does not appear to be different than that used by EPA third party contractors (e.g., Eastern Research Group etc.).

Section 2.2 – Attachment A to the Letter Dated October 24 2000

- 2.2.1. *Several category headings are confusing. For instance, how does a “Count” differ from a “Counting Run.” The significance of the category “Percentage of Total Anglers Intercepted for Exit Interviews” is questionable, because it is based on the “Total Number of Anglers Catching fish or crabs (including missed creel reports)” as a percentage of “Total Number of Anglers Intercepted for Exit Interviews.” A more relevant category would be the number of anglers interviewed as a percentage of the total number of anglers on the River or shore.*

*CLH Response: There is no difference between a “Count” and a “Counting Run.” Both terms refer to one trip between the northern and southern boundaries of the Study Area.

The purpose of statistics such as the “percentage of total anglers intercepted for exit interviews” is merely to reflect daily response rates and is not intended to be indicative of the relative number of anglers present in the Study Area that are interviewed during the survey period. CLH agrees that a statistic reflecting the number of anglers interviewed as the percentage of the total number of anglers on the river would be interesting and will consider developing such a statistic.

- 2.2.2. *At the meeting with CLH in October 2000, CLH’s consultants indicated that the response rate thus far was 90%. However, the data in this document indicates a response rate of 68%.*

CLH Response: There is no discrepancy between these two figures. At the October 2000 meeting with EPA, CLH’s consultants indicated that the response rate for first-time respondents was 90% and that the overall response rate was 68%. The 68% figure includes first-time respondents as well as previously interviewed respondents.

Section 3 – Revised Creel Angler Study Work Plan

- 3.1. *We agree that biota move in and out of the study area. This document provides some detail on the movement of the blue-clawed crab from the study area into Newark Bay, as well as upriver of the Study Area. As such, we are concerned that individuals outside of the six-mile “operable unit” may consume crabs (and other biota) and therefore be exposed. This was discussed in our previous letter. We regularly conduct analyses of exposure routes that are outside the real property*

boundaries of an operable unit. For example, at sites with ground water contaminant plumes, we collect data from residential wells downgradient of the real property from which the ground water plume emanates and conduct response actions where residential wells have been contaminated. We analyze the risk of residents utilizing such tap water from activities such as drinking and showering. Organisms that have been contaminated due to their residence and/or migration through the study area that can be consumed by other organisms in other locations, including anglers, must be included in the risk assessment. Thus, if CLH is conducting a survey of anglers that are potentially exposed to fish or other biota that may reside or migrate through the study area, the survey must be representative of all such anglers. This is another reason that similar surveys in other areas of the Newark Bay Complex are important to the risk assessment. Therefore, CLH's unwillingness to include angling locations near the study area, yet beyond the physical boundaries of it, clearly ignores a population of exposed individuals.

Further, the restrictions to the study area are artificial based on the movements of the crabs and fish and the knowledge from the Exposure Factor's Handbook (EFH) that individuals are willing to travel 34 miles for fishing. Since the baseline risk assessment needs to address future use of the river, this approach would likely underestimate the risks.

CLH Response: EPA cannot change the scope of the AOC and the RI/FS by comments to the CASWP. The AOC and SOW are on their face clearly limited to the Passaic River Study Area. At paragraph 33, the AOC provides that it is both "ordered and agreed that Respondent shall undertake a RI/FS with respect to the Site." The AOC defines "Site" as the "Passaic River Study Area," which in turn is defined as "...that portion of the Passaic River from the abandoned ConRail Railroad bridge at the downriver boundary of the Area located at the U.S. Army Corps of Engineers ("USACE") station designation of 40+00 (i.e., a transect running perpendicular to the USACE Federal Project Limit for dredging 4000 feet upstream from the red channel junction marker at the confluence of the Hackensack and Passaic Rivers) to a transect six miles (31680 feet) upriver located at the USACE station designation of 356+80."

The SOW in turn very clearly states that one of the three specified Goals of the Work to be Performed is to "Determine the primary human and ecological receptors . . . in the Passaic River Study Area." The goal clearly says "in the Study Area," not there and wherever else EPA may later suggest be studied as part of this RI/FS. Under this Goal is a statement that this information is necessary to identify potential direct and indirect impacts to humans and the ecology, to identify receptors of greatest concern, and *inter alia*, to identify short- and long- term risks and establish appropriate action levels. This was specifically agreed to by both EPA and CLH during the negotiations that resulted in this AOC and SOW and EPA and CLH understood clearly, as is

documented, that the RI/FS, including the Risk Assessment, is limited to the six mile Passaic River Study Area. This comment is out of order and seeks to ignore the plain meaning and intent of the AOC as negotiated and agreed to by both EPA and CLH.

- 3.2. *Page 1-4 fails to acknowledge that fish advisories are currently in place as part of the Study Area Setting. Based on our previous discussions and letters on this subject, it is clear that some of the published literature reports that fish advisories bias results of creel surveys and others report that the existence of advisories do not. Apparently, human behavior is extremely difficult to quantify. The existence of the advisories should simply be noted. It can also be noted that NJDEP scientists working in the Newark Bay Complex, including the study area, have found that anglers in this area do not seem to change their fishing habits or responses to the survey because of the existence of the advisories. This finding is something that we should explore further because apparently, the utilization of a passive measure such as placement of "no fishing" signs does not do an adequate job of protecting public health.*

CLH Response: While page 1-4 of the CASWP does not specifically state that fish advisories are currently in place, CLH recognizes that they are and designed the survey and questionnaires with that recognition. CLH will revise the language on page 1-4 of the CASWP to state that fish-consumption advisories are currently in place for the Study Area.

With respect to the comment that CLH should also note that NJDEP scientists have found that anglers in this area do not seem to change their fishing habits because of advisories, please refer to page 1-15 of the CASWP where this is already noted:

"The Kirk Phlugh *et al.* (1999) study concluded that although most of the anglers interviewed had heard of the fish and crab consumption advisories, they could not state the advisories correctly, and they either did not believe or were unconcerned about health effects from eating contaminated fish or crabs."

With respect to the comment on quantifying the effect of advisories on human behavior, Questions 21 and 22 of the Exit-Interview Questionnaire are specifically designed to quantify the level of advisory knowledge and the impact that knowledge has on human behavior for anglers continuing to fish in the Study Area. Stated specifically, the questions are the following:

Question 21: Do you know if the state of New Jersey has warned people not to eat fish and crabs caught in this part of the river? Yes
No

Question 22: (asked only of those answering yes to Question 21)
Because of these warnings, have you

A.	Eaten fewer fish from this area?	Yes	No
B.	Eaten fewer crabs from this area?	Yes	No
C.	Fished less in this area?	Yes	No
D.	Crabbed less in this area?	Yes	No

Results from these questions not only document the level of advisory knowledge, but also the behavioral changes on trip and consumption frequency as a result of advisory knowledge. If desired, the results of this information can then be used in the Feasibility Study.

- 3.3. *Pages 1-6, 1-13, and 3-3 specifically emphasize quantifying the size of the exposed population. The size of the exposed population (the population risk) is not relevant to baseline risk assessments being developed in conformance with the NCP. Superfund risk assessments are based on exposures to the RME or CT Individual.*

*CLH Response: This response is similar to the response to Comment 1.4.1.

On the contrary, numerous EPA guidance documents discuss the importance of population risk (USEPA, 1997, 1992, 1989). Estimation of population risk is a critical component of risk characterization and, pursuant to USEPA guidance, it will be addressed in the Human and Ecological Risk Assessment (HERA). Population risk is typically estimated by multiplying the individual risk by the size of the potentially exposed population. It yields an expected increase in the number of adverse health effects for a given population size. For the HERA, it will serve as an important metric because it will provide the interested parties (the public, the agency, and the respondent) with an understanding of the overall risk to the fish consuming and general population. It also provides a measurement endpoint that can be evaluated by an epidemiological analysis.

Numerous EPA guidance documents specifically mention calculation of population risk. For example, the USEPA 1989 Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual, states:

“...if the size of the potentially exposed population is large, the presentation of the population numbers may be of assistance to the RPM, especially in evaluating risks in the context of current land use” (p 8-26).

As stated in the USEPA 1992 Guidance on Risk Characterization for Risk Managers and Risk Assessors:

“EPA risk assessments will be expected to address or provide descriptions of population risk” (p 21).

“Regarding exposure and risk characterization, it is Agency policy to present information on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (i.e., central tendency, high end of individual risk, *population risk*, important subgroups if known)...”. “*This guidance applies to all Agency offices.*” (p. 5, italics added).

Finally, and of greatest relevance and importance, the USEPA 1997 Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories gives detailed and explicit guidance on methods for calculating population risk for cancer and noncancer effects:

“2.5.1 Carcinogenic Toxicity

Population Risk

The estimated population cancer risk is calculated by multiplying the number of people in an exposure group (with the same exposure) by the lifetime cancer risks calculated from the equation above. The population risk equation is:

$$(\text{population cancer risk}) = \text{lifetime risk} \times (\text{size of exposed population})$$

For example, if 5,000 people are exposed at a risk level of one per thousand (1×10^{-3}) (per lifetime), the overall risk to that population is five additional cancer cases ($5,000 \times 1 \times 10^{-3} = 5$) over the background level.” (p. 2-60)

“2.5.2 Noncarcinogenic Toxicity

Population Risk

The population risk is expressed as the number of individuals with exposure levels greater than the RfD:

Noncarcinogenic risk = population with exposure greater than the RfD” (p. 2-62).

For the sake of brevity, we have not listed all the excerpts from all the EPA guidance documents that discuss the importance of population risk. However, it is clear that EPA Superfund guidance, guidance for risk managers, and guidance specific to fish consumption risk assessments recommend the evaluation of population risk.

- 3.4. *On page 1-7, it is important to note that the RME is defined as greater than the 90th percentile of the distribution. Also, on page 1-8, the upper percentile for angler consumption rates should be based on the 90th percentile or above.*

*CLH Response: CLH acknowledges that EPA guidance defines the RME as exposure above the 90th percentile of the distribution and that, according to EPA guidance, a high-end exposure factor value is one that is at or above the 90th percentile. However, it is not clear where EPA would like discussion to this effect inserted, particularly given that at the pages noted in the CASWP, the existing discussion concerns potential subpopulations. CLH would welcome clarification of this comment by EPA.

- 3.5. *Page 1-8 indicates an “event-by-event” exposure analysis will be developed for the exposure assessment. This is insufficient. Consideration must be given to the potential for individuals to freeze crabs and fish for consumption in the future. The questionnaire simply does not include this potential exposure route. Further, an event-by-event exposure may underestimate fish consumption since information on fish consumption over longer periods is not asked. Further, nothing is asked about consumption during the lifetime that may indicate future activity patterns. The use of models national probability approaches and/or extrapolation of such information introduces additional uncertainty that could be addressed by simply collecting the information.*

CLH Response: First, as discussed in the response to comment 1.8.1, the event-by-event exposure analysis with trips as the event does not limit consumption to the day of the trip. Fish or crabs cannot be consumed in the future unless harvested on a successful trip. Whether the fish or crabs were consumed fresh on the day of the trip or following a period of storage or freezing, the total amount of fish consumed from that trip is accounted for when measuring consumption in reference to the trip.

Second, CLH disagrees with EPA’s opinions that “event-by-event exposure [assessment] may underestimate fish consumption since information on fish

consumption over longer periods is not asked” and “nothing is asked about consumption during the lifetime that may indicated future activity patterns.” In addition to collecting information about the specific trip during which the angler is interviewed, there are questions in the CAS regarding trip-taking frequency, months fished during the year, and years fished, all of which relate to activity patterns for fishing trips that are related to fish-consumption rates. As discussed in detail in the response to comment 1.2.1, the approach adopted in the CAS, in contrast to EPA’s recommended series of questions, is expected to minimize recall and estimation burden on anglers while providing a strong foundation for developing long-term consumption rates needed for risk assessment.

- 3.6. *Please clarify what census data and published information regarding fishing practices near the Study Area CLH proposes to use in determining the existence of subpopulations during data analysis.*

*CLH Response: The exact information to be used will depend on what is available at the time the analysis is conducted and what is agreed upon in the development of risk assessment protocols. CLH will use the most recent and disaggregate census data available. If the 2000 Census data are available by town and zip code at the time of our analysis, they will be used. If not, we will use more aggregate 2000 data, such as demographics by county. The primary source of information, however, is expected to be the CAS data.

- 3.7. *Page 1-9 suggests there are always cooking losses. However, two studies (Moya et al., 1998 and Ambruster et al., 1987) found no loss, and, in fact, found an increase in concentration. Further, there is also a potential that an individual will consume the pan drippings where the contaminants are supposedly, “lost.” Pan drippings are commonly incorporated into sauces, for example. Therefore, the assumption that all contaminants are lost during cooking is simply erroneous. Certainly, there may be cases that there is some loss and the risk assessment can therefore evaluate various circumstances (losses, increases, and no changes).*

*CLH Response: The response to Comment 1.12.1 discusses cooking loss, which is a matter for the risk assessment. Based on the literature cited in the CASWP, CLH recognizes that some cooking methods may result in no loss of chemicals. If, for example, the angler’s preferred cooking method is making fish soup, then no cooking loss would be expected. Nothing in the text of the CASWP implies that “all contaminants are lost during cooking” as EPA has asserted in its comment. However, in response to this comment, CLH will

clarify the language in Section 1.3.2 of the CASWP to read "the cooking loss, if any, associated with the angler's preferred cooking method."

Cooking loss is typically represented as the fraction of chemical mass that is lost from the consumed portion of fish. The minimum cooking loss is 0; that is, the cooking process cannot *add* chemicals to fish that were not present in the raw fish. That some studies found an increase in *concentration* after cooking does not imply that the *mass* of chemicals increased.

- 3.8. *On page 1-12, it is unclear how the portion size for an individual is derived from the measured fish/shellfish reported on the interview form in Appendix C. This includes size of fillets, tomale or internal organs. Provide the rationale or explanation as to how the survey will differentiate between a large person and a small person, a male or female, or a child of 14 versus a child of 2; it simply isn't evident on the form.*

*CLH Response: Both the Exit Interview form and Missed Creel Report record the gender of the angler. The Exit Interview form collects information on the number of fish or crab consumers who are children, women, and pregnant or nursing women. The Missed Creel Report also collects information on anglers younger than 18. As is common in surveys of this type, the portion sizes for individuals, including children and women, will be determined by dividing the edible portion of fish or crab equally among the number of consumers reported. Edible portions will be determined based on parts reported consumed and the fractions of total fish or crab weight they contribute, based on a combination of site-specific and literature studies. As discussed in the response to Comment 1.3.2, total fish or crab weight will be determined using field measurements of fish and crabs combined with length-weight relationships based on site-specific data and the literature. As for relative sizes of consumers (e.g., body weights for use in dose estimation), it is expected that these will be estimated as part of the risk assessment process using standard literature sources and EPA guidance (e.g., *Exposure Factors Handbook*).

- 3.9. *Page 1-12 indicates that the fraction of the fish /shellfish eaten by an individual will be obtained, in part, by using a portion size approach model for several portion sizes. It is unclear whether or not there will be physical models used and whether or not this information is going to be captured. If consumption will be derived by a mathematical or extrapolation model, explain how the portion size data will be generated.*

CLH Response: The response to Comment 1.3.1 explains that portion size models will not be used in the CAS. The response to Comment 3.8 indicates how portion sizes will be determined.

- 3.10. *On page 1-13, the discussion indicates that a wide variety of cooking methods will be evaluated. It is important to note that there is limited data on the impacts of these cooking practices on the concentrations of contaminants in fish and crabs for a large number of potential contaminants. In the event that information is not available regarding the specific cooking practice, explain how cooking losses will be evaluated in the risk assessment. Also, explain how specific ethnic cooking practices will be addressed in the assessment.*

*CLH Response: The responses to Comments 1.12.1 and 3.7 address cooking loss issues, which are a matter for the risk assessment. As for "specific ethnic cooking practices," if any are identified via the exit interview data from the CAS, they can be considered in the risk assessment.

- 3.11. *On page 2-3, the specialties of the technical team does not include a Social Scientist. Explain why a Social Scientist was not included.*

CLH Response: The CASWP states, "a multidisciplinary technical team was used to develop the CASWP and will be maintained to oversee the implementation of the CAS. This team includes experts in the field of risk assessment, statistics, fisheries biology, and public survey design and administration." Although the term "social scientist" is not listed specifically, many social scientists are working on the CAS. They include, but are not limited to, the following:

Nicholas A. Holt, Ph.D.
Senior Vice President
Roper Starch Worldwide, Inc.
Director of Survey Administration
Degrees: B.A. Sociology and Biology, M.S. Sociology, Ph.D. Sociology.

Robert G. Benford
Senior Research Director
Roper Starch Worldwide, Inc.
Survey Administration Manager

Degrees: A.S. Metallurgical Engineering Technology, B.S. Agricultural Business Management, M.S. Survey Methodology

William H. Desvousges, Ph.D.

President

Triangle Economic Research

Project Support and Development

Degrees: B.A. Economics, M.S. Economics, and Ph.D. Economics.

Richard W. Dunford, Ph. D.

Vice President

Triangle Economic Research

Project Support and Development

Degrees: B.A. Economics, M.A. Economics, M.A. Agricultural Economics, and Ph.D. Agricultural Economics.

Kevin Boyle, Ph.D.

Expert Panel Member

Degrees: B.A. Economics, M.S. Agricultural and Resource Economics, and Ph.D. Agricultural Economics.

Jason C. Kinnell, M.S.

Senior Economist

Triangle Economic Research

Project Manager

Degrees: B.S. Economics and Mathematics, M.S. Agricultural Economics

Margaret S. Lieberman, M.A.

Economist

Triangle Economic Research

Project Support

Degrees: B.A. Economics, M.A. Economics

- 3.12. *On page 2-6, explain how "survey drift" will be addressed. The document is unclear as to when datasheets will be excluded from the survey and the procedure for determining that certain data be removed. This should be clarified with a decision tree that describes the procedure for excluding datasheets.*

CLH Response: As stated on page 30 of CLH's *Response to January 27, 2000 EPA Informal Comments on the Draft Creel/Angler Survey Work Plan (Prepared June 2000)*, "none of CLH's contractors, including survey experts, knows what "drift" in survey technique means...per the explanation provided, there are no modifications to the Draft CASWP required to address this

comment.” As in CLH’s June 2000 response, assuming “drift” relates to survey continuity, continuity will be addressed through several methods. First, there are supervisors in the field overseeing the implementation of the On-Site Count and On-Site Interview procedures. Second, procedural training was conducted prior to the survey’s start and at a point prior to the survey’s Spring administration. Third, all members of the survey staff have been provided with a copy of the CAS Procedures Manual. The manual is a 130-page document describing the details of all survey-administration procedures. Fourth, once the data leaves the Study Area, they are validated and coded for data entry. The validation process ensures that the specified data-collection procedures were followed and that there are no errors in the data prior to data entry. Fifth, the data are double key entered and reconciled against the paper data to ensure that the data were accurately transferred from paper to electronic form.

With respect to excluding datasheets, CLH assumes “datasheets” is referring to the three types of data-collection forms: the Angler/Crabber Counts Form, the Exit-Interview questionnaire, and the Missed Creel Report. We do not expect to exclude any datasheets collected from observations within the Study Area. Every data sheet collected will contain either a set of observations for a particular counting run, an on-site interview, or a missed creel report.

- 3.13. *On page 3-11 the discussion of identifying individuals by race (i.e., White and Non-White) and then recording race on the Count Form is unclear and subject to significant misclassification errors. Care must be taken in categorizing individuals based on race and ethnicity. For example, in 1976 the Office of Management and Budget of defined Hispanic as “ethnicity” and not race. It is more appropriate to ask individuals to identify their own race and/or ethnicity rather than asking the surveyors/data collectors to identify it. An individual's race and/or ethnicity should not be assumed as indicated in this survey. Since it is unclear how this information will be used in the assessment, consideration should be given to not collecting this information in the survey without specific justification regarding need.*

A Social Scientist should be consulted regarding the appropriate definitions of the various populations and the terms that these individuals prefer for their ethnic group.

CLH Response: With respect to recording race, page 3-11 of the CASWP states, “Finally, the counters will record the individual’s race by circling W for white and NW for non-white. If the person is non-white, the counters will try to determine the person’s race and will write it in the blank next to the NW in addition to circling NW.” For anglers in the NW category, the counters, “try to determine the person’s race,” as a means of providing supplemental

data that can be used for the analysis. For example, if the counters determine that the individual is black, they circle NW and write "Black" on the line provided. If they determine that the individual appears to be of Asian descent, they circle NW and write in "Asian." If the counter cannot determine anything more specific than non-white, then the counter does not complete the line after NW. The provision of this additional procedure allows for the collection of a potentially richer data set with respect to race. Moreover, the fact that the counters collect race in two broad categories is indicative of the fact that we recognize the difficulty and subjectivity of assigning rather than asking race.

With respect to the comment that it is more appropriate to ask individuals to identify their race, the counters are collecting their data from a boat, not on land. The pretest results indicated that anglers prefer not to be approached by boat (CASWP, Section 3.1.1 and November 3, 2000 Passaic CAS Pretest Report). Therefore, the counter's data are observational data only. The exit-interview team, which is located on the shoreline at one of the five public-access points, collects interview data. When interviewing respondents, the interviewers ask the individuals to provide their race.

Numerous social scientists (see response to comment 3.11) were consulted regarding the various race classifications. They recommended that the boat-based team record race as white or non-white, letting the counters provide more information on non-white if the counters felt they could make an accurate assessment. The social scientists also recommended that CLH provide the categories in Question 25 including an open-ended Other category that the interviewer can complete and a Don't Know category. During the On-Site Interview, the participants assign themselves to the appropriate race. The interview protocol instructs the interviewer to be extremely sensitive to the angler's comfort level and offer respondents the opportunity to write in their respective category (CASWP, Section 3.2.5.1).

- 3.14. *On page 3-21, the fact that the questions are restricted to only a part of this estuarine river is unacceptable; EPA will be considering future exposures in the risk assessment, as well as anglers in other locations on the river, and in the Newark Bay Complex.*

CLH Response: EPA cannot change the scope of the AOC and the RI/FS by comments to the CASWP. The AOC and SOW on their face are clearly limited to the Passaic River Study Area. At paragraph 33, the AOC provides that it is both "ordered and agreed that Respondent shall undertake a RI/FS with respect to the Site." The AOC defines "Site" as the "Passaic River Study Area," which in turn is defined as "...that portion of the Passaic River from the

abandoned ConRail Railroad bridge at the downriver boundary of the Area located at the U.S. Army Corps of Engineers ("USACE") station designation of 40+00 (i.e., a transect running perpendicular to the USACE Federal Project Limit for dredging 4000 feet upstream from the red channel junction marker at the confluence of the Hackensack and Passaic Rivers) to a transect six miles (31680 feet) upriver located at the USACE station designation of 356+80."

The SOW in turn very clearly states that one of the three specified Goals of the Work to be Performed is to "Determine the primary human and ecological receptors . . . in the Passaic River Study Area." The goal clearly says "in the Study Area," not there and wherever else EPA may later suggest be studied as part of this RI/FS. Under this Goal is a statement that this information is necessary to identify potential direct and indirect impacts to humans and the ecology, to identify receptors of greatest concern, and *inter alia*, to identify short- and long- term risks and establish appropriate action levels. This was specifically agreed to by both EPA and CLH during the negotiations that resulted in this AOC and SOW and EPA and CLH understood clearly, as is documented, that the RI/FS, including the Risk Assessment, is limited to the six mile Passaic River Study Area. This comment is out of order and seeks to ignore the plain meaning and intent of the AOC as negotiated and agreed to by both EPA and CLH.

- 3.15. *On page 3-27, the previous concerns regarding race and ethnicity (comment 13) need to be addressed.*

*CLH Response: CLH agrees that assigning ethnicity or race is potentially subjective. Many steps have been taken to ensure that the data are as reliable as possible and that we do not overstate the data's reliability.

The team from the professional survey firm responsible for data collection, led by social scientist Dr. Nicholas Holt, provided initial definitions of the various ethnic and racial groups. Responses of pretest participants confirmed the terms that these anglers prefer for referring to their ethnic and racial groups. During the On-Site Interview, the participants assign themselves to the appropriate ethnicity or race. Our interview protocol instructs the interviewer to be extremely sensitive to the angler's comfort level and offer participants the opportunity to write their respective category instead of stating it (CASWP, Section 3.2.5.1). During the pretest both Spanish-speaking and Portuguese-speaking anglers assigned themselves as "Hispanic" in race (November 3, 2000, Pretest Report, Section 1.1).

The pretest results show that anglers do not like to be approached by boats for several reasons (CASWP, Section 3.1.1.). This makes it impossible for anglers observed from the boat to self-identify their ethnicity to the count team. The On-Site Count protocol explains that the counters should differentiate between white and non-white and, if possible, write the race in the blank if non-white. The counters must use their best judgment to determine race for non-white individuals. If race cannot be determined, the counters will leave the blank next to Non-White empty (CASWP, Section 3.1.8). It was decided that collecting more reliable information, with potentially less detail, was better than collecting unreliable information.

The Missed Creel Report protocol instructs the interviewer to circle the race of the individual. If the race is not listed, the administrator will circle "Other" and write the corresponding race. If the interviewer cannot determine the angler's race, the interviewer will circle "Don't Know" (CASWP, Section 3.2.6). As with the On-Site Count protocol, it was decided that the benefits of collecting more reliable information, with potentially less detail, was better than collecting unreliable information.

This information will be used during the interpretation and analysis of CAS data in the risk assessment to determine whether subsistence or other potentially sensitive subpopulations are present in the Study Area.

- 3.16. *Chapter 4 discusses a Monte Carlo strategy for evaluating areas for intercepting anglers. It has not yet been determined that a Monte Carlo approach will be used. Therefore, EPA defers its comments regarding a Monte Carlo strategy at this time.*

*CLH Response: Chapter 4 of the CASWP describes a Monte Carlo simulation that was employed during development of the CAS in order to aid in choosing the number of days on which to interview and enumerate anglers, as well as how to distribute these sampling days across the CAS year's seasons, months, types of days (i.e., weekdays vs. weekend days), and times of day. The purpose of this simulation was to statistically determine the optimal number and allocation of days to ensure both complete coverage of all combinations of seasons, months, types of days, and times of day and to maximize the probability of intercepting anglers. The Monte Carlo simulation was only one of several techniques used to determine and validate the optimal sampling plan for implementation in the CAS. Appendix E of the CASWP includes a full description of the Monte Carlo methodology employed for this purpose.

Any Monte Carlo approach used in the risk assessment would be different from that used for evaluating strategies for sampling in the CAS. CLH agrees that discussions regarding specific risk assessment methods should be deferred to the risk assessment protocol process.

- 3.17. *On page 4-5, a citation for the STATA program should be provided.*

CLH Response: The citation for the STATA program is:

StataCorp. 2001. *Stata Statistical Software: Release 7.0*. College Station, TX: Stata Corporation.

CLH will add this citation to the revised CASWP.

- 3.18. *Explain how the data collected on an angler's family members will be incorporated into the risk assessment. Explain how portion sizes will be developed for other family members.*

CLH Response: The response to Comment 3.8 discusses how portion sizes will be determined. The Exit Interview form does not include any questions about family members. Rather, the angler is asked how many people will be consuming the fish and/or crabs, including the angler. The relationship between the people who consume fish and/or crabs from the Study Area is not necessary for risk assessment purposes. Information collected during the interview regarding whether children or pregnant or nursing women are consumers of the fish will be used to determine whether members of these potentially sensitive subpopulations are exposed to fish and crabs from the Passaic River Study Area.

- 3.19. *On pages 5-1 and 5-2, mention is made that "Additional data analysis to support quantification of the fish/crab consumption exposure pathways will be performed as part of the risk assessment" but no details are provided. No information is provided regarding how the data from the survey will be analyzed to develop consumption rates for the risk assessment. It is important that this be presented in this document.*

*CLH Response: The CASWP, like other elements of the ESP, is a workplan for collection of data to support RI/FS activities. In addition, like other ESP

elements, the CASWP was developed based on prior knowledge of data needs, uses, and quality objectives. Other ESP sampling plans have not included detailed information on how data will be analyzed and used in RI/FS activities. The specific details of the procedures for analyzing and interpreting CAS data were anticipated to be part of the risk assessment process and presented in the risk assessment report. However, because of strong interest in this information at this time, CLH is preparing a Data Analysis Plan on an accelerated schedule. The Data Analysis Plan is based on prior knowledge of the uses and quality needs of the data. A draft of the Data Analysis Plan is currently under review by the expert panel CLH has convened to assist with design and interpretation of the CAS. CLH will provide the Data Analysis Plan to EPA once it is finalized to the satisfaction of the expert panel. The Data Analysis Plan will be included with the submittal of the Creel Angler Survey Report, which will document the administration of the CAS and provide tabulated results and limited, summary statistics.

- 3.20. *On the survey form, the following questions must be incorporated:*
- Where else do you fish or crab?*
 - When did you start fishing or crabbing?*
 - Why did you throw fish back?*
 - Do you freeze crabs or fish for later consumption?*
 - How many people are living in the household? (For use in calculating a Poverty Index Ratio).*
 - Do you consume the crab butter (hepatopancreas)?*

With regards to the educational questions, explain how individuals with no school or only grammar school will be identified.

CLH Response: The questions listed above are not essential for inclusion in the CAS.

- Other locations fished or crabbed by anglers are irrelevant for the risk assessment of the Passaic River Study Area.
- The CAS already asks anglers how many years they have fished at the Study Area; starting age for fishing from any site is irrelevant.
- The reason for throwing fish and/or crabs back is also irrelevant to risk assessment, since the angler's trip to the Study Area will not result in any fish/crab consumption.
- As discussed in responses to Comments 1.8.1 and 3.5, there is no need to ask questions specifically about storage or freezing of fish

because any consumption of stored or frozen fish from the trip is covered in determining a consumption rate based on the trip as the event. Data are collected on all kept fish, regardless of when they will be consumed.

- Calculating a poverty index ratio is not an objective of the CAS, so no questions regarding household size are necessary. However, the number of consumers of the angler's fish, which is needed for determining consumption rates, is asked.
- The exit interview presently includes a question (part of Question 20, the catch table) about whether crab "mustard" is consumed. The term "mustard" was recognized and understood to be the hepatopancreas by anglers who participated in the survey pretest. Hence, there is no reason to ask about crab "butter," which refers to the same part as "mustard."

When asked questions about education level, if anglers indicate that none of the categories included on the form is applicable, the interviewer can write in the angler's response (e.g., no school or grammar school only).

- 3.21. *There may be confidentiality issues related to the listing of the phone number. Provide and explain the type of follow-up questions anticipated in follow-up phone calls.*

CLH Response: Asking respondents for their telephone number is not for potential reinterview but rather a means to get an individual characteristic that can be used to help match up anglers over time if they complete multiple interviews. The interviewers do not pressure anglers to report their telephone number and if an angler refuses to provide a telephone number, the interviewers will ask for only the first six digits of the number (i.e., area code and prefix). These first six digits potentially provide enough variation to differentiate the angler from other anglers (CASWP, Section 3.2.5.1).

- 3.22. *On page E-6, explain why these steps are only repeated 30 times.*

CLH Response: The Monte Carlo sampling simulation described in Appendix E of the CASWP states that 5,000 iterations were used to generate points on the sampling distribution for each of the 3 candidate sampling plans, resulting in 15,000 total points. This process was then repeated 30 times resulting in

450,000 points over which the results were averaged in order to compare the accuracy of each candidate sampling plan. The concept of obtaining a larger data set in order to increase the accuracy of estimates is based on a fundamental theory of statistics, the law of large numbers. The law of large numbers states that as the number of observations in a sample grows large, the probability of the sample representing the true population approaches one (i.e., the sample approaches its asymptotic distribution). An obvious question is what constitutes a "large" number. While no general rule exists to answer this question, studies have shown that samples as small as 30 may be large enough to approximate the asymptotic distribution of an estimator (Goldfield & Quandt, 1972). In this application, since the 30 repetitions are used on a sample of 15,000 observations, or 5,000 observations per candidate sampling plan, the total number of observations is clearly large enough for any standard of accuracy of the resulting estimates.

The purpose of this simulation was to statistically determine the optimal number and allocation of days to ensure both complete coverage of all combinations of seasons, months, types of days, and times of day and to maximize the probability of intercepting anglers. The Monte Carlo simulation was only one of several techniques used to determine and validate the optimal sampling plan for implementation in the CAS.

3.23. *On page E-15, explain why these steps run 5,000 times and not 10,000 times.*

CLH Response: As in the previous response, the law of large numbers states that as the number of observations in a sample grows large, the probability of the sample representing the true population approaches one (i.e., the sample approaches its asymptotic distribution). An obvious question is what constitutes a "large" number. While no general rule exists to answer this question, studies have shown that samples as small as 30 may be large enough to approximate the asymptotic distribution of an estimator (Goldfield & Quandt, 1972). According to Chebyshev's Inequality the difference between using a sample of 5,000 repetitions versus 10,000 repetitions is approximately equivalent to the difference in scaling the accuracy of the estimates by 1/5,000 instead of 1/10,000 or the difference between .0002 and .0001 (i.e., a difference of one-thousandth).

3.24. *On page E-20, statistical methods are proposed. Such statistical methods may not adequately capture the tidal nature of the area. The reliance on a purely statistical procedure to select sampling dates/times will not be reflective of the actual angling patterns. There would be some statistical chance that the pre-determined time to*

conduct the survey could sometimes fall when the tide is moving up the river. However, a better approach would be either to determine during what portion of the tidal cycle anglers prefer to fish, perhaps dependent upon species sought, or to assure that during the course of the investigation all tidal cycles are adequately represented. Without this, the method may underestimate the number of anglers found during the survey.

CLH Response: The comment that statistical methods may not adequately capture the tidal nature of the area is incorrect. The sampling plan being implemented samples all possible tidal regimes, seasons, times of day, and days of the week. CLH has followed the second approach proposed above, which is to ensure that all tidal regimes are represented during the course of the investigation. CLH believes that this method maximizes the probability of encountering the entire range of anglers in the Study Area and accounts for anglers' respective preferences for fishing or crabbing. The sampling method is stratified by season, month, day type (weekday, weekend, or holiday), and time of day (early shift or late shift). Furthermore, this sampling plan is extremely extensive, sampling 150 days out of a one-year period or 41 percent of the year. In addition, since the tide cycle is only 6 hours, the 8 hour shift length of the CAS sampling plan ensures that at least two phases of the tide are observed each time the CAS team is present in the Study Area. Therefore, this sampling plan provides enough variation to cover all tidal regimes regardless of the portion of the tidal cycle anglers prefer to fish.

- 3.25. *No questions are included in the survey to address an individual that reports that the crab they have caught is not for consumption. If an individual has caught a crab and kept it, and they report that it is not for consumption, it is appropriate to ask why they are keeping it and what its intended use is. The hypothesis provided at the meeting, that the crab would be used as fishing bait, seems inconsistent with other population groups use of crabs. Perhaps the question should be asked regarding the activities in more detail ("Can you tell me specifically what you plan to do with the crab?"). If reported to be used as bait, ask the individual to describe the procedure to prepare the crab for bait and what species they are trying to catch with the crab.*

CLH Response: The CAS's On-Site Interview form includes a question addressing fate of fish and crabs that are not for consumption. The catch table beneath Question 20 on the On-Site Interview form has a column containing the question "What about fish not eaten?" for recording the fate of uneaten kept catch. While the question does not explicitly state fish/shellfish, the columns surrounding it do address both fish and shellfish. Implicitly, this column is intended to refer to both fish and shellfish and the interview team presents this question as referring to all catch, regardless of species, when

interviewing anglers. Moreover, each row of the table is completed for a particular species type. Therefore, if the respondent is keeping crabs, the interviewer records the number and length of each crab and then begins asking all the remaining questions in the table, continually referring to the angler's kept crabs.

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